ANNEX I

LIST OF THE NAMES, PHARMACEUTICAL FORMS, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTES OF ADMINISTRATION, MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES

Member State	**Marketing Authorisation Holder**	**Invented name**	**Strength**	**Pharmaceutical Form**	**Route of administration**	**Content (concentration)**
Austria	UCB Pharma GmbH (AT) Jacquingasse,16-18/3.OG 1030 Wien	Zyrtec 10 mg - Filmtabletten	10mg	film-coated tablet	oral use	
Austria	UCB Pharma GmbH (AT) Jacquingasse,16-18/3.OG 1030 Wien	Zyrtec 10 mg/ml – Tropfen	10mg/ml	oral drops, solution	oral use	10mg/ml
Austria	UCB Pharma GmbH (AT) Jacquingasse,16-18/3.OG 1030 Wien	Zyrtec 1 mg/ml – orale Lösung	1mg/ml	oral solution	oral use	1mg/ml
Belgium	McNeil Roderveld 1 B – 2600 Berchem Belgium	REACTINE	10mg	film-coated tablet	oral use	
Belgium	UCB Pharma SA (Brussels) Allée de la Recherche, 60 B-1070 Brussels	CETIRIZINE-UCB	10mg	film-coated tablet	oral use	
Belgium	UCB Pharma SA (Brussels) Allée de la Recherche, 60 B-1070 Brussels	CETIRIZINE-UCB	10mg/ml	oral drops, solution	oral use	10mg/ml
Belgium	UCB Pharma SA (Brussels) Allée de la Recherche, 60 B-1070 Brussels	VIRLIX	10mg/ml	oral drops, solution	oral use	10mg/ml
Belgium	UCB Pharma SA (Brussels) Allée de la Recherche, 60 B-1070 Brussels	ZYRTEC	10mg	film-coated tablet	oral use	
Belgium	UCB Pharma SA (Brussels) Allée de la Recherche, 60 B-1070 Brussels	ZYRTEC	10mg/ml	oral drops, solution	oral use	10mg/ml

Member State	**Marketing Authorisation Holder**	**Invented name**	**Strength**	**Pharmaceutical Form**	**Route of administration**	**Content (concentration)**
Belgium	UCB Pharma SA (Brussels) Allée de la Recherche, 60 B-1070 Brussels	ZYRTEC	1mg/ml	oral solution	oral use	1mg/ml
Bulgaria	UCB Farchim S.A. (AG, Ltd) Z.I. de Planchy Ch. de Croix-Blanche 10 CH-1630 Bulle	ZYRTEC	10mg	film-coated tablet	oral use	
Bulgaria	UCB Farchim S.A. (AG, Ltd) Z.I. de Planchy Ch. de Croix-Blanche 10 CH-1630 Bulle	ZYRTEC	10mg/ml	oral drops, solution	oral use	10mg/ml
Cyprus	Lifepharma (Z.A.M.) Ltd (CY) 8 Ayiou Nicolaou Street P.O. Box 22679 1523 Nicosia Cyprus	ZYRTEC	10mg	film-coated tablet	oral use	
Cyprus	Lifepharma (Z.A.M.) Ltd (CY) 8 Ayiou Nicolaou Street P.O. Box 22679 1523 Nicosia Cyprus	ZYRTEC	1mg/ml	oral solution	oral use	1mg/ml
Czech Republic	UCB Pharma SA (BRAINE) Chemin du Foriest Braine-l'Alleud B-1420 Belgium	ZYRTEC	10mg	film-coated tablet	oral use	
Czech Republic	UCB Pharma SA (BRAINE) Chemin du Foriest Braine-l'Alleud B-1420 Belgium	ZYRTEC	10mg/ml	oral drops, solution	oral use	10mg/ml

Member State	**Marketing Authorisation Holder**	**Invented name**	**Strength**	**Pharmaceutical Form**	**Route of administration**	**Content (concentration)**
Denmark	McNeil Denmark Aps Bregnerødvej 133 DK-3460 Birkerød	BENADAY	10mg	film-coated tablet	oral use	
Denmark	McNeil Denmark Aps Bregnerødvej 133 DK-3460 Birkerød	BENADAY	1mg/ml	oral solution	oral use	1mg/ml
Denmark	UCB Nordic A/S (DK) Arne Jacobsens Allé 15 DK-2300 Kobenhavn S	ZYRTEC	10mg	film-coated tablet	oral use	
Denmark	UCB Nordic A/S (DK) Arne Jacobsens Allé 15 DK-2300 Kobenhavn S	ZYRTEC	10mg/ml	oral drops, solution	oral use	10mg/ml
Denmark	UCB Nordic A/S (DK) Arne Jacobsens Allé 15 DK-2300 Kobenhavn S	ZYRTEC	1mg/ml	oral solution	oral use	1mg/ml
Estonia	UCB Pharma Oy Finland Malminkaari 5 FI-00700 HELSINKI	ZYRTEC	10mg	film-coated tablet	oral use	
Estonia	UCB Pharma Oy Finland Malminkaari 5 FI-00700 HELSINKI	ZYRTEC	10mg/ml	oral drops, solution	oral use	10mg/ml
Estonia	UCB Pharma Oy Finland Malminkaari 5 FI-00700 HELSINKI	ZYRTEC	1mg/ml	oral solution	oral use	1mg/ml
Finland	McNeil, a division of Janssen-Cilag Oy Metsänneidonkuja 8 02130 ESPOO	BENADAY	10mg	film-coated tablet	oral use	
Finland	UCB Pharma Oy Finland Malminkaari 5 FI-00700 HELSINKI	ZYRTEC	10mg	film-coated tablet	oral use	

Member State	**Marketing Authorisation Holder**	**Invented name**	**Strength**	**Pharmaceutical Form**	**Route of administration**	**Content (concentration)**
Finland	UCB Pharma Oy Finland Malminkaari 5 FI-00700 HELSINKI	ZYRTEC	10mg/ml	oral drops, solution	oral use	10mg/ml
Finland	UCB Pharma Oy Finland Malminkaari 5 FI-00700 HELSINKI	ZYRTEC	1mg/ml	oral solution	oral use	1mg/ml
France	Pfizer Santé Grand Public (FR) 23-25 avenue du docteur Lannelongue 75668 Paris cedex 14	REACTINE	10mg	film-coated tablet	oral use	
France	Sanofi Aventis France 9 Boulevard Romain Rolland 75159 Paris Cedex 14 France	VIRLIX	10mg	film-coated tablet	oral use	
France	Sanofi Aventis France 9 Boulevard Romain Rolland 75159 Paris Cedex 14 France	VIRLIX	10mg/ml	oral drops, solution	oral use	10mg/ml
France	Sanofi Aventis France 9 Boulevard Romain Rolland 75159 Paris Cedex 14 France	VIRLIX	1mg/ml	oral solution	oral use	1mg/ml
France	UCB Pharma S.A.21, Rue de Neuilly F-92003 Nanterre	CETIRIZINE UCB 10MG	10mg	film-coated tablet	oral use	
France	UCB Pharma S.A.21, Rue de Neuilly F-92003 Nanterre	ZYRTEC	10mg	film-coated tablet	oral use	
France	UCB Pharma S.A.21, Rue de Neuilly F-92003 Nanterre	ZYRTEC	10mg/ml	oral drops, solution	oral use	10mg/ml

Member State	**Marketing Authorisation Holder**	**Invented name**	**Strength**	**Pharmaceutical Form**	**Route of administration**	**Content (concentration)**
France	UCB Pharma S.A.21, Rue de Neuilly F-92003 Nanterre	ZYRTEC	1mg/ml	oral solution	oral use	1mg/ml
France	Pfizer Santé Grand Public (FR) 23-25 avenue du docteur Lannelongue 75668 Paris cedex 14	ACTIFED ALLERGIE CETIRIZINE 10MG	10mg	film-coated tablet	oral use	
France	UCB Pharma S.A.21, Rue de Neuilly F-92003 Nanterre	ZYRTECSET	10 mg	film-coated tablet	oral use	
Germany	UCB GmbH Alfred-Nobel-Str. 10 D-40789 Monheim Germany	ZYRTEC	10mg	film-coated tablet	oral use	
Germany	UCB GmbH Alfred-Nobel-Str. 10 D-40789 Monheim Germany	ZYRTEC P	10mg	film-coated tablet	oral use	
Germany	UCB GmbH Alfred-Nobel-Str. 10 D-40789 Monheim Germany	ZYRTEC P TROPFEN	10mg/ml	oral drops, solution	oral use	10mg/ml
Germany	UCB GmbH Alfred-Nobel-Str. 10 D-40789 Monheim Germany	ZYRTEC SAFT	1mg/ml	oral solution	oral use	1mg/ml
Germany	UCB GmbH Alfred-Nobel-Str. 10 D-40789 Monheim Germany	ZYRTEC TROPFEN	10mg/ml	oral drops, solution	oral use	10mg/ml

Member State	**Marketing Authorisation Holder**	**Invented name**	**Strength**	**Pharmaceutical Form**	**Route of administration**	**Content (concentration)**
Germany	Pfizer Consumer Healthcare GmbH Pfizerstr. 1 D-76139 Karlsruhe GERMANY	REACTINE	10mg	film-coated tablet	oral use	
Greece	UCB A.E. 580 Avenue Vouliagmenis GR-16452 Argyroupoli Athens	ZIPTEK	10mg	film-coated tablet	oral use	
Greece	UCB A.E. 580 Avenue Vouliagmenis GR-16452 Argyroupoli Athens	ZIPTEK	10mg/ml	oral drops, solution	oral use	10mg/ml
Hungary	UCB Magyarország Kft Árpád fejedelem útja 26-28 1023 Budapest Hungary	ZYRTEC CSEPPEK	10mg/ml	oral drops, solution	oral use	10mg/ml
Hungary	UCB Magyarország Kft Árpád fejedelem útja 26-28 1023 Budapest Hungary	ZYRTEC FILMTABLETTA	10mg	film-coated tablet	oral use	
Hungary	UCB Magyarország Kft Árpád fejedelem útja 26-28 1023 Budapest Hungary	ZYRTEC OLDAT	1mg/ml	oral solution	oral use	1mg/ml
Hungary	UCB Magyarország Kft Árpád fejedelem útja 26-28 1023 Budapest Hungary	ZYRTEC START FILMTABLETTA	10mg	film-coated tablet	oral use	
Ireland	UCB Pharma Ireland Limited, United Drug House, Magna Drive City West Road Dublin 24 Ireland	ZIRTEK ORAL SOLUTION 1MG/ML	1mg/ml	oral solution	oral use	1mg/ml

Member State	**Marketing Authorisation Holder**	**Invented name**	**Strength**	**Pharmaceutical Form**	**Route of administration**	**Content (concentration)**
Ireland	UCB Pharma Ireland Limited, United Drug House, Magna Drive City West Road Dublin 24 Ireland	ZIRTEK TABLETS	10mg	film-coated tablet	oral use	
Italy	Istituto Lusofarmaco Via Walter Tobagi 8 20068 Peschiera Borromeo (MI) Italy	FORMISTIN	10mg	film-coated tablet	oral use	
Italy	Istituto Lusofarmaco Via Walter Tobagi 8 20068 Peschiera Borromeo (MI) Italy	FORMISTIN	10mg/ml	oral drops, solution	oral use	10mg/ml
Italy	Pfizer Consumer Healthcare S.r.l. SS 156km 50 04010 Borgo San Michele (LT) Italy	VIRLIX	10mg	film-coated tablet	oral use	
Italy	Pfizer Consumer Healthcare S.r.l. SS 156km 50 04010 Borgo San Michele (LT) Italy	VIRLIX	10mg/ml	oral drops, solution	oral use	10mg/ml
Italy	UCB Pharma SpA Via Praglia, 15 I-10044 Pianezza (Torino)	ZIRTEC 1 MG/ML SOLUZIONE ORALE	1mg/ml	oral solution	oral use	1mg/ml
Italy	UCB Pharma SpA Via Praglia, 15 I-10044 Pianezza (Torino)	ZIRTEC 10 MG COMPRESSE RIVESTITE CON FILM	10mg	film-coated tablet	oral use	

Member State	**Marketing Authorisation Holder**	**Invented name**	**Strength**	**Pharmaceutical Form**	**Route of administration**	**Content (concentration)**
Italy	UCB Pharma SpA Via Praglia, 15 I-10044 Pianezza (Torino)	ZIRTEC 10 MG/ML GOCCE ORALI SOLUZIONE	10mg/ml	oral drops, solution	oral use	10mg/ml
Latvia	UCB Pharma Oy Finland Malminkaari 5 FI-00700 HELSINKI	ZYRTEC	10mg	film-coated tablet	oral use	
Latvia	UCB Pharma Oy Finland Malminkaari 5 FI-00700 HELSINKI	ZYRTEC	10mg/ml	oral drops, solution	oral use	10mg/ml
Latvia	UCB Pharma Oy Finland Malminkaari 5 FI-00700 HELSINKI	ZYRTEC	1mg/ml	oral solution	oral use	1mg/ml
Lithuania	UCB Pharma Oy Finland Malminkaari 5 FI-00700 HELSINKI	ZYRTEC	10mg	film-coated tablet	oral use	
Lithuania	UCB Pharma Oy Finland Malminkaari 5 FI-00700 HELSINKI	ZYRTEC	10mg/ml	oral drops, solution	oral use	10mg/ml
Lithuania	UCB Pharma Oy Finland Malminkaari 5 FI-00700 HELSINKI	ZYRTEC	1mg/ml	oral solution	oral use	1mg/ml
Luxemburg	McNeil Roderveld 1 B – 2600 Berchem Belgium	REACTINE	10mg	film-coated tablet	oral use	
Luxemburg	McNeil Roderveld 1 B – 2600 Berchem Belgium	Sinutab Decongestif & Antihistaminicum	5mg	film-coated tablet	Oral use	

Member State	**Marketing Authorisation Holder**	**Invented name**	**Strength**	**Pharmaceutical Form**	**Route of administration**	**Content (concentration)**
Luxemburg	UCB Pharma SA (Brussels) Allée de la Recherche, 60 B-1070	VIRLIX	10mg/ml	oral drops, solution	oral use	10mg/ml
Luxemburg	UCB Pharma SA (Brussels) Allée de la Recherche, 60 B-1070	ZYRTEC	10mg	film-coated tablet	oral use	
Luxemburg	UCB Pharma SA (Brussels) Allée de la Recherche, 60 B-1070	ZYRTEC	10mg/ml	oral drops, solution	oral use	10mg/ml
Luxemburg	UCB Pharma SA (Brussels) Allée de la Recherche, 60 B-1070	ZYRTEC	1mg/ml	oral solution	oral use	1mg/ml
Luxemburg	UCB Pharma SA (Brussels) Allée de la Recherche, 60 B-1070	CETIRIZINE-UCB	10mg	film-coated tablet	oral use	
Luxemburg	UCB Pharma SA (Brussels) Allée de la Recherche, 60 B-1070	CETIRIZINE-UCB	10mg/ml	oral drops, solution	oral use	10mg/ml
Malta	Pharmasud Ltd. 38 Triq L-Isturnell San Gwann SGN02 Malta	ZYRTEC	10mg	film-coated tablet	oral use	
Malta	Pharmasud Ltd. 38 Triq L-Isturnell San Gwann SGN02 Malta	ZYRTEC	1mg/ml	oral solution	oral use	1mg/ml
Netherlands	Pfizer Consumer Healthcare BV Rivium Westlaan 142 NL-2909 LD Capelle a/d IJsel Nederland	REACTINE	10mg	film-coated tablet	oral use	

Member State	**Marketing Authorisation Holder**	**Invented name**	**Strength**	**Pharmaceutical Form**	**Route of administration**	**Content (concentration)**
Netherlands	UCB Pharma B.V. Lage Mosten 33 NL-4822 NK Breda Nederland	ZYRTEC	10mg	film-coated tablet	oral use	
Netherlands	UCB Pharma B.V. Lage Mosten 33 NL-4822 NK Breda Nederland	ZYRTEC	1mg/ml	oral solution	oral use	1mg/ml
Norway	McNeil Sweden AB, Sollentuna Sweden	REACTINE	10mg	film-coated tablet	oral use	
Norway	UCB Nordic A/S (DK) Arne Jacobsens Allé 15 DK-2300 Kobenhavn S	ZYRTEC	10mg	film-coated tablet	oral use	
Norway	UCB Nordic A/S (DK) Arne Jacobsens Allé 15 DK-2300 Kobenhavn S	ZYRTEC	10mg/ml	oral drops, solution	oral use	10mg/ml
Norway	UCB Nordic A/S (DK) Arne Jacobsens Allé 15 DK-2300 Kobenhavn S	ZYRTEC	1mg/ml	oral solution	oral use	1mg/ml
Poland	Pfizer Consumer Healthcare (GB) Walton Oaks Dorking Road, Walton on the Hill KT 20 7 NS, Surrey Great Britain	REACTINE	10mg	film-coated tablet	oral use	
Poland	PLIVA Kraków Zakłady Farmaceutyczne S.A. ul. Mogilska 80 31-546 Krakow Poland	VIRLIX	10mg	film-coated tablet	oral use	

Member State	**Marketing Authorisation Holder**	**Invented name**	**Strength**	**Pharmaceutical Form**	**Route of administration**	**Content (concentration)**
Poland	PLIVA Kraków Zakłady Farmaceutyczne S.A. ul. Mogilska 80 31-546 Krakow Poland	VIRLIX	1mg/ml	oral solution	oral use	1mg/ml
Poland	Vedim Sp.z.o.o. Ul. Kruczkowskiego, 8 00 - 380 Warszawa Poland	ZYRTEC	10mg	film-coated tablet	oral use	
Poland	Vedim Sp.z.o.o. Ul. Kruczkowskiego, 8 00 - 380 Warszawa Poland	ZYRTEC	10mg/ml	oral drops, solution	oral use	10mg/ml
Poland	Vedim Sp.z.o.o. Ul. Kruczkowskiego, 8 00 - 380 Warszawa Poland	ZYRTEC	1mg/ml	oral solution	oral use	1mg/ml
Poland	Vedim Sp.z.o.o. Ul. Kruczkowskiego, 8 00 - 380 Warszawa Poland	ZYRTEC UCB	10mg	film-coated tablet	oral use	
Portugal	UCB Pharma Ed. Maria I, Q 60, piso 1 A Quinta da Fonte 2770-229 PACO DE ARCOS	ZYRTEC	10mg	film-coated tablet	oral use	
Portugal	UCB Pharma Ed. Maria I, Q 60, piso 1 A Quinta da Fonte 2770-229 PACO DE ARCOS	ZYRTEC	10mg/ml	oral drops, solution	oral use	10mg/ml

Member State	**Marketing Authorisation Holder**	**Invented name**	**Strength**	**Pharmaceutical Form**	**Route of administration**	**Content (concentration)**
Portugal	UCB Pharma Ed. Maria I, Q 60, piso 1 A Quinta da Fonte 2770-229 PACO DE ARCOS	ZYRTEC	1mg/ml	oral solution	oral use	1mg/ml
Portugal	Vedim Pharma Lda Ed. D. Maria I Piso 1 A Quinta da Fonte 2770-229 Paco de Arcos Portugal	VIRLIX	10mg	film-coated tablet	oral use	
Portugal	Vedim Pharma Lda Ed. D. Maria I Piso 1 A Quinta da Fonte 2770-229 Paco de Arcos Portugal	VIRLIX	1mg/ml	oral solution	oral use	1mg/ml
Romania	UCB GmbH Huttenstraße 205 D-50170 Kerpen Germany	ZYRTEC	10mg	film-coated tablet	oral use	
Romania	UCB GmbH Huttenstraße 205 D-50170 Kerpen Germany	ZYRTEC	10mg/ml	oral drops, solution	oral use	10mg/ml
Slovakia	UCB SA Pharma Secteur Chemin du Foriest, B-1420 Braine l´Alleud Belgium	ZYRTEC GTT POR 10MG/ML	10mg/ml	oral drops, solution	oral use	10mg/ml
Slovakia	UCB SA Pharma Secteur Chemin du Foriest, B-1420 Braine l´Alleud Belgium	ZYRTEC TBL FLM 10MG	10mg	film-coated tablet	oral use	

Member State	**Marketing Authorisation Holder**	**Invented name**	**Strength**	**Pharmaceutical Form**	**Route of administration**	**Content (concentration)**
Slovenia	Medis Podjetje za proizvodnjo in trzenje, D.O.O. (Slovenia) Brnciceva 1 SLO - 1001 Ljubljiana Slovenia	ZYRTEC 1 MG/ML PERORALNA RAZTOPINA	1mg/ml	oral solution	oral use	1mg/ml
Slovenia	Medis Podjetje za proizvodnjo in trzenje, D.O.O. (Slovenia) Brnciceva 1 SLO - 1001 Ljubljiana Slovenia	ZYRTEC 10 MG FILMSKO OBLOZENE TABLETE	10mg	film-coated tablet	oral use	
Slovenia	Medis Podjetje za proizvodnjo in trzenje, D.O.O. (Slovenia) Brnciceva 1 SLO - 1001 Ljubljiana Slovenia	ZYRTEC 10 MG/ML PERORALNE KAPLJICE, RAZTOPINA	10mg/ml	oral drops, solution	oral use	10mg/ml
Spain	Laboratorios Menarini S.A. Alfonso XII, 587 08918 Badalona (Barcelona) Spain	ALERLISIN	10mg	film-coated tablet	oral use	
Spain	Laboratorios Menarini S.A. Alfonso XII, 587 08918 Badalona (Barcelona) Spain	ALERLISIN	10mg/ml	oral drops, solution	oral use	10mg/ml
Spain	Laboratorios Menarini S.A. Alfonso XII, 587 08918 Badalona (Barcelona) Spain	ALERLISIN	1mg/ml	oral solution	oral use	1mg/ml
Spain	Lacer SA Sardenya 346 - 350 E - 08025 Barcelona Spain	VIRDOS	10mg/ml	oral drops, solution	oral use	10mg/ml

Member State	**Marketing Authorisation Holder**	**Invented name**	**Strength**	**Pharmaceutical Form**	**Route of administration**	**Content (concentration)**
Spain	Lacer SA Sardenya 346 - 350 E - 08025 Barcelona Spain	VIRLIX	10mg	film-coated tablet	oral use	
Spain	Lacer SA Sardenya 346 - 350 E - 08025 Barcelona Spain	VIRLIX	1mg/ml	oral solution	oral use	1mg/ml
Spain	Pfizer Consumer Healthcare Plaza Xavier Cugat, 2. Edificio D. E-08174. Sant Cugat del Vallés. Barcelona	REACTINE	10mg	film-coated tablet	oral use	
Spain	Pfizer Consumer Healthcare Plaza Xavier Cugat, 2. Edificio D. E-08174. Sant Cugat del Vallés. Barcelona	REACTINE 5MG/5ML SOLUCIÓN ORAL	1mg/ml	oral solution	oral use	1mg/ml
Spain	UCB Pharma S.A. Avenida de Barcelona 239 E-08750 Molins de Rei	ZYRTEC COMPRIMIDOS RECUBIERTOS CON PELICULA	10mg	film-coated tablet	oral use	
Spain	UCB Pharma S.A. Avenida de Barcelona 239 E-08750 Molins de Rei	ZYRTEC GOTAS ORALES EN SOLUCIÓN	10mg/ml	oral drops, solution	oral use	10mg/ml
Spain	UCB Pharma S.A. Avenida de Barcelona 239 E-08750 Molins de Rei	ZYRTEC SOLUCIÓN ORAL	1mg/ml	oral solution	oral use	1mg/ml

Member State	**Marketing Authorisation Holder**	**Invented name**	**Strength**	**Pharmaceutical Form**	**Route of administration**	**Content (concentration)**
Spain	Vedim Pharma S.A. Avenida de Barcelona, 239 08750 Molins de Rei (Barcelona) Spain	ALERRID 10 MG COMPRIMIDOS RECUBIERTO CON PELICULA	10mg	film-coated tablet	oral use	
Sweden	UCB Nordic A/S Arne Jacobsens Allé 15 DK-2300 Kobenhavn S Denmark	ALERID	10mg	film-coated tablet	oral use	
Sweden	UCB Nordic A/S Arne Jacobsens Allé 15 DK-2300 Kobenhavn S Denmark	ZYRLEX	10mg	film-coated tablet	oral use	
Sweden	UCB Nordic A/S Arne Jacobsens Allé 15 DK-2300 Kobenhavn S Denmark	ZYRLEX	10mg/ml	oral drops, solution	oral use	10mg/ml
Sweden	UCB Nordic A/S Arne Jacobsens Allé 15 DK-2300 Kobenhavn S Denmark	ZYRLEX	1mg/ml	oral solution	oral use	1mg/ml
United Kingdom	McNeil Products Limited Foundation Park, Roxborough way, Maidenhead, Berkshire, SL6 3UG, UK	BENADRYL ALLERGY ORAL SYRUP	1mg/ml	oral solution	oral use	1mg/ml
United Kingdom	McNeil Products Limited Foundation Park, Roxborough way, Maidenhead, Berkshire, SL6 3UG, UK	BENADRYL FOR CHILDREN ALLERGY SOLUTION	1mg/ml	oral solution	oral use	1mg/ml

Member State	**Marketing Authorisation Holder**	**Invented name**	**Strength**	**Pharmaceutical Form**	**Route of administration**	**Content (concentration)**
United Kingdom	McNeil Products Limited Walton Oaks, Dorking Road, Walton on the Hill, Surrey KT20 7NS UK	BENADRYL ONE A DAY	10mg	film-coated tablet	oral use	
United kingdom	McNeil Products Limited Foundation Park, Roxborough way, Maidenhead, Berkshire, SL6 3UG, UK	BENADRYL ONE A DAY RELIEF	10mg	film-coated tablet	oral use	
United Kingdom	UCB PHARMA LIMITED 208 Bath Road SLOUGH Berkshire SL1 3WE	ZIRTEK ALLERGY RELIEF FOR CHILDREN	1mg/ml	oral solution	oral use	1mg/ml
United Kingdom	UCB PHARMA LIMITED 208 Bath Road SLOUGH Berkshire SL1 3WE	ZIRTEK ALLERGY RELIEF TABLETS	10mg	film-coated tablet	oral use	
United Kingdom	UCB PHARMA LIMITED 208 Bath Road SLOUGH Berkshire SL1 3WE	ZIRTEK ALLERGY SOLUTION	1mg/ml	oral solution	oral use	1mg/ml
United Kingdom	UCB PHARMA LIMITED 208 Bath Road SLOUGH Berkshire SL1 3WE	BENADRYL ALLERGY SOLUTION	1mg/ml	oral solution	oral use	1mg/ml

Member State	**Marketing Authorisation Holder**	**Invented name**	**Strength**	**Pharmaceutical Form**	**Route of administration**	**Content (concentration)**
United Kingdom	UCB PHARMA LIMITED 208 Bath Road SLOUGH Berkshire SL1 3WE	BENADRYL ALLERGY ORAL SOLUTION	1mg/ml	oral solution	oral use	1mg/ml

ANNEX II

SCIENTIFIC CONCLUSIONS AND GROUNDS FOR THE SUMMARIES OF PRODUCT CHARACTERISTICS, LABELLING AND PACKAGE LEAFLET PRESENTED BY THE EMEA

SCIENTIFIC CONCLUSIONS

OVERALL SUMMARY OF THE SCIENTIFIC EVALUATION OF ZYRTEC AND ASSOCIATED NAMES (SEE ANNEX I)

Zyrtec (cetirizine dihydrochloride) is an antiallergic drug indicated for the relief of nasal symptoms of seasonal and perennial allergic rhinitis. The drug is authorised for the symptomatic treatment of seasonal allergic rhinitis, perennial allergic rhinitis, and various types of pruritus and dermatological conditions from allergic origin, in particular chronic idiopathic urticaria. In adults, all three indications are treated by a 10 mg daily dose of cetirizine. The drug is indicated in adults and children aged 2 years and older in all the member states. In 16 member states, treatment with cetirizine is also recommended in infants and toddlers aged 1 to 2 years. The liquid formulations are primarily for children up to 12 years, the solid tablets are for children from 12 years on and for adults. Due to the divergent national decisions taken by Member States concerning the authorisation of Zyrtec, a number of divergences exist in the product information and a referral was therefore triggered by the European Commission Article 30 of Directive 2001/83/EC as amended in order to harmonise the divergent Product Information texts across the EU. A list of Questions was adopted by the CHMP, highlighting the main areas of divergences.

The CHMP asked the MAH to revise the wording, restrict and define the indication in rhinoconjunctivitis rather than in conjunctivitis alone and discuss seasonal conjunctivitis, itching and allergic pruritis, severe skin reactions induced by mosquito and atopic dermatitis, as they should be considered as separate entities requiring more supportive data.

The MAH acknowledged that the indication section varies a lot from one Member State to the other but that the wording differences corresponded to three well-identified indications. The MAH provided extensive testing data from the review of therapeutic trials and the corresponding clinical study reports in support of these indications and proposed the removal of the other indications such as atopic dermatitis, prevention of asthma, mosquito bites as the clinical evidences available to support these indications was considered insufficient. The corresponding section of the PL was revised accordingly. The following indications were agreed upon:

In adults, children, infants and toddlers 2 year and above:

- *Cetirizine is indicated for the relief of nasal and ocular symptoms of seasonal and perennial allergic rhinitis*
- *Cetrizine is indicated for the relief of chronic idiopathic urticaria.*

The current paediatric indications are not disharmonised based on the indication itself but with regards to the definition of the paediatric age groups and with regards to the dosing for these groups. Depending on the member state, the posology is based on the weight or the age, or even a combination of both and a number of age groups and posology groups were identified. The MAH argued that the paediatric use of cetirizine in the same indications as in adults is justified, as no pathophysiological reason was identified for not using antihistamines in the paediatric population, provided the dose is adequately adapted to different body weight, age and clearance of the drug. A harmonized wording for age groups and relevant posology was agreed upon:

- *Children aged from 2 to 6 years: 2.5 mg twice daily (5 drops twice daily).*
- *Children aged from 6 to 12 years: 5 mg twice daily (10 drops twice daily).*
- *Adults and adolescents over 12 years of age: 10 mg once daily (20 drops).*

The posology proposed for children has been tested in clinical trials, but also results from dosing adaptations based on body weight and clearance that varies according to the maturation of the renal system. This is why the harmonized wording does not propose a weight – based posology, as weight is clearly not the only factor to define the dose.

The MAH was also asked to provide data in support of the recommended dosing in patients with renal impairment and provide justifications for the benefit/risk ratio of halving the dose. The systemic exposure with half doses is not documented and insufficient efficacy related to half doses may lead the patients to cumulate other treatments. The MAH was also asked to justify the dosing in paediatric patients suffering from renal impairment and the dosing by weight in the 2-5 year age group and dosing by age groups 2-5, 6-11 and 12-18 as well as dosing for children less than 2 years old.

The MAH stated that the clinical benefit/risk ratio of cetirizine has not been specifically evaluated in patients with renal impairment and that the dose is therefore based on pharmacokinetic calculations only. No signal suggesting an unfavourable benefit/risk ratio for Zyrtec compared to other anti-histamines was ever detected in pharmacovigilance during the 22 years on the market; however the MAH would like to retain the contraindication: *"Patients with severe renal impairment at less than 10 ml/min creatinine clearance."*

For children with renal impairment, the clinical effects or the pharmacokinetics of cetirizine have never been tested but the MAH agreed that the current wording is not entirely correct since the age of the patient is important as it determines its clearance. The sentence will therefore be adapted to: *"In paediatric patients suffering from renal impairment, the dose will have to be adjusted on an individual basis taking into account the renal clearance of the patient, his age, and his body weight"*

Regarding the dosing by weight, the MAH responded that systemic exposure to cetirizine is not only a function of body weight but also of renal clearance of the drug, with studies demonstrating that clearance is more important when age is low. The doses proposed for registration have been demonstrated as being safe and effective in many trials performed in children 2 to 12 years old, as reviewed in the clinical expert report provided in the MAH dossier. Regarding the dosing by age group, the MAH defended the same dosing for age group 12 to 18 as in adults because the increase in body weight is compensated by a decrease in clearance, allowing for an equivalent systemic exposure. Regarding dosage under the age of 2, the MAH justified the dosing based on PK data. The CHMP agreed that no safety or toxicity issues with the use of cetirizine in renal failure have been identified over the many years of clinical experience; however the CHMP adopted a lower age limit of 2 years for the use of cetirizine.

The MAH also proposed harmonised Product Information texts for section 4.3 Contraindications reflecting the hypersensitivity to formulation constituents and addressing patients with severe renal impairment. The Product Information of the tablet and the oral formulations also reflected the additional contraindication related to the excipients. The MAH also reviewed the remaining divergent contra-indications.

The MAH proposed a harmonised text for section 4.4 Special Warnings, as the section was extensively disharmonised and added some warnings regarding the suitability of the formulations for certain age ranges and reflecting the lack of appropriate data on the benefit- risk for children below one year old, restricting the use of film-coated tablets in children aged less than 6 years, the use of the oral solution children aged less than 2 years and the use of the drop formulation in infants and toddlers aged less than 1 year old. In addition, the MAH agreed to include a warning for the drop formulation, stating that the confirmation of the diagnosis by a practitioner specialized in allergy should be sought before starting a treatment with cetirizine in children under the age of 2, as symptoms of viral infections of the upper respiratory system are misinterpreted as allergic in this age group. The CHMP agreed with the harmonised text but maintained its lower age limit of 2 years.

The MAH was asked to revise section 4.5 Interaction with other medicinal products, as no pharmacokinetic interactions are awaited with this substance, since it is not metabolised and two third of the ingested dose are eliminated unchanged in urine. According to the guideline of the SPC, negative interactions should be mentioned in the SPC only if they are of clinical interest to the prescriber. The MAH agreed with the CHMP recomendations but considered that the sentence on food interaction should be retained as it is independent from the liver enzymes interactions.

The MAH also reworded the entire section 4.8 Undesirable effects in accordance with current guidelines and with the QRD comments received. In particular, frequencies were added to the listing of events, as observed from pharmacovigilance surveys. The MAH however informed the CHMP that due to the need for translating the old terms into the new ones, the process must start by a recoding of the source documents. The CHMP acknowledged the problem of translating from old to new formats and the MAH's division of events into frequencies observed in clinical trials and frequencies estimated from post marketing experience could be agreed upon.

Regarding section 5.1 Pharmacodynamic properties, the MAH was asked to reword section 5.1 and retain only the properties that are relevant with regards to the therapeutic effects. The experimental effects observed in animals or at higher than recommended doses and not in line with the indication should be deleted. The MAH agreed to the text proposed by the CHMP.

GROUNDS FOR AMENDMENT OF THE SUMMARIES OF PRODUCT CHARACTERISTICS, LABELLING AND PACKAGE LEAFLET

Whereas

- the scope of the referral was the harmonisation of the Summaries of Products Characteristics, labelling and package leaflet,

- the Summaries of Products Characteristic, labelling and package leaflet proposed by the Marketing Authorisation Holders have been assessed based on the documentation submitted and the scientific discussion within the Committee,

the CHMP has recommended the amendment of the Marketing Authorisations for which the Summary of Product Characteristics, labelling and package leaflet are set out in Annex III for Zyrtec and associated names (see Annex I).

ANNEX III

SUMMARY OF PRODUCT CHARACTERISTICS, LABELLING AND PACKAGE LEAFLET

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Zyrtec 10 mg film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One film-coated tablets contains 10 mg cetirizine dihydrochloride

Excipients: one film-coated tablet contains 66.40 mg lactose-monohydrate

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Film-coated tablets

White, oblong, film-coated tablet, with breakline and Y-Y logo

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

In adults and paediatric patients 6 year and above:

- Cetirizine is indicated for the relief of nasal and ocular symptoms of seasonal and perennial allergic rhinitis.
- Cetirizine is indicated for the relief of symptoms of chronic idiopathic urticaria.

4.2 Posology and method of administration

Children aged from 6 to 12 years: 5 mg twice daily (a half tablet twice daily).

Adults and adolescents over 12 years of age: 10 mg once daily (1 tablet).

The tablets need to be swallowed with a glass of liquid.

Elderly subjects: data do not suggest that the dose needs to be reduced in elderly subjects provided that the renal function is normal.

Patients with moderate to severe renal impairment: there are no data to document the efficacy/safety ratio in patients with renal impairement. Since cetirizine is mainly excreted via renal route (see section 5.2), in cases no alternative treatment can be used, the dosing intervals must be individualized according to renal function. Refer to the following table and adjust the dose as indicated. To use this dosing table, an estimate of the patient's creatinine clearance (CL_{cr}) in ml/min is needed. The CL_{cr} (ml/min) may be estimated from serum creatinine (mg/dl) determination using the following formula:

$$CL_{cr} = \frac{[140 - age(years)]\, x\, weight\,(kg)}{72\, x\, serum\, creatinine\,(mg/dl)} (x\, 0.85\ for\ women)$$

Dosing adjustments for adult patients with impaired renal function

Group	Creatinine clearance (ml/min)	Dosage and frequency
Normal	≥80	10 mg once daily
Mild	50 – 79	10 mg once daily
Moderate	30 – 49	5 mg once daily
Severe	30	5 mg once every 2 days
End-stage renal disease - Patients undergoing dialysis	10	Contra-indicated

In pediatric patients suffering from renal impairment, the dose will have to be adjusted on an individual basis taking into account the renal clearance of the patient, his age and his body weight.

Patients with hepatic impairment: no dose adjustment is needed in patients with solely hepatic impairment.

Patients with hepatic impairment and renal impairment: dose adjustment is recommended (see Patients with moderate to severe renal impairment above).

4.3 Contraindications

Hypersensitivity to the active substance, to any of the excipients, to hydroxyzine or to any piperazine derivatives.

Patients with severe renal impairment at less than 10 ml/min creatinine clearance.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose- galactose malabsorption should not take cetirizine film-coated tablet.

4.4 Special warnings and precautions for use

At therapeutic doses, no clinically significant interactions have been demonstrated with alcohol (for a blood alcohol level of 0.5 g/L). Nevertheless, precaution is recommended if alcohol is taken concomitantly.

Caution in epileptic patients and patients at risk of convulsions is recommended.

The use of the film-coated tablet formulation is not recommended in children aged less than 6 years since this formulation does not allow for appropriate dose adaptation.

4.5 Interaction with other medicinal products and other forms of interaction

Due to the pharmacokinetic, pharmacodynamic and tolerance profile of cetirizine, no interactions are expected with this antihistamine. Actually, neither pharmacodynamic nor significant pharmacokinetic interaction was reported in drug-drug interactions studies performed, notably with pseudoephedrine or theophylline (400 mg/day).

The extent of absorption of cetirizine is not reduced with food, although the rate of absorption is decreased.

4.6 Pregnancy and lactation

For cetirizine very rare clinical data on exposed pregnancies are available. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/fetal development, parturition or postnatal development. Caution should be exercised when prescribing to pregnant or breast feeding women because cetirizine passes into breast milk.

4.7 Effects on ability to drive and use machines

Objective measurements of driving ability, sleep latency and assembly line performance have not demonstrated any clinically relevant effects at the recommended dose of 10 mg.
Patients intending to drive, engaging in potentially hazardous activities or operating machinery should not exceed the recommended dose and should take their response to the medicinal product into account. In these sensitive patients, concurrent use with alcohol or other CNS depressants may cause additional reductions in alertness and impairment of performance.

4.8 Undesirable effects

Clinical studies have shown that cetirizine at the recommended dosage has minor undesirable effects on the CNS, including somnolence, fatigue, dizziness and headache. In some cases, paradoxical CNS stimulation has been reported.

Although cetirizine is a selective antagonist of peripheral H_1-receptors and is relatively free of anticholinergic activity, isolated cases of micturition difficulty, eye accommodation disorders and dry mouth have been reported.

Instances of abnormal hepatic function with elevated hepatic enzymes accompanied by elevated bilirubin have been reported. Mostly this resolves upon discontinuation of the treatment with cetirizine dihydrochloride.

Clinical trials

Double blind controlled clinical or pharmacoclinical trials comparing cetirizine to placebo or other antihistamines at the recommended dosage (10 mg daily for cetirizine), of which quantified safety data are available, included more than 3200 subjects exposed to cetirizine.
From this pooling, the following adverse events were reported for cetirizine 10 mg in the placebo-controlled trials at rates of 1.0 % or greater:

Adverse event (WHO-ART)	**Cetirizine 10 mg (n= 3260)**	**Placebo (n = 3061)**
Body as a whole – general disorders		
Fatigue	1.63 %	0.95 %
Central and peripheral nervous system disorders		
Dizziness	1.10 %	0.98 %
Headache	7.42 %	8.07 %
Gastro-intestinal system disorders		
Abdominal pain	0.98 %	1.08 %
Dry mouth	2.09 %	0.82 %
Nausea	1.07 %	1.14 %
Psychiatric disorders		
Somnolence	9.63 %	5.00 %
Respiratory system disorders		
Pharyngitis	1.29 %	1.34 %

Although statistically more common than under placebo, somnolence was mild to moderate in the majority of cases. Objective tests as demonstrated by other studies have demonstrated that usual daily activities are unaffected at the recommended daily dose in healthy young volunteers.

Adverse drug reactions at rates of 1 % or greater in children aged from 6 months to 12 years, included in placebo-controlled clinical or pharmacoclinical trials are:

Adverse drug reactions (WHO-ART)	Cetirizine (n=1656)	Placebo (n =1294)
Gastro-intestinal system disorders Diarrhoea	1.0 %	0.6 %
Psychiatric disorders Somnolence	1.8 %	1. 4 %
Respiratory system disorders Rhinitis	1.4 %	1.1 %
Body as a whole – general disorders Fatigue	1.0 %	0.3 %

Post-marketing experience

In addition to the adverse effects reported during clinical studies and listed above, isolated cases of the following adverse drug reactions have been reported in post-marketing experience. For these less frequently reported undesirable effects, the estimated frequencies (uncommon: ≥1/1,000 to 1/100, rare: ≥1/10,000 to 1/1,000, very rare: 1/10,000) are made based on post-marketing experience.

Blood and lymphatic disorders:
Very rare: thrombocytopenia

Immune system disorders:
Rare: hypersensitivity
Very rare: anaphylactic shock

Psychiatric disorders:
Uncommon: agitation
Rare: aggression, confusion, depression, hallucination, insomnia
Very rare: tic

Nervous system disorders:
Uncommon: paraesthesia
Rare: convulsions, movements disorders
Very rare: dysgeusia, syncope, tremor, dystonia, dyskinesia

Eye disorders:
Very rare: accommodation disorder, blurred vision, oculogyration

Cardiac disorders:
Rare: tachycardia

Gastro-intestinal disorders:
Uncommon: diarrhoea

Hepatobiliary disorders:
Rare: hepatic function abnormal (increased transaminases, alkaline phosphatase, γ-GT and bilirubin)

Skin and subcutaneous tissue disorders:
Uncommon: pruritus, rash
Rare: urticaria
Very rare: angioneurotic oedema, fixed drug eruption

Renal and urinary disorders:
Very rare: dysuria, enuresis

General disorders and administration site conditions:
Uncommon: asthenia, malaise
Rare: oedema

Investigations:
Rare: weight increased

4.9 Overdose

Symptoms

Symptoms observed after an overdose of cetirizine are mainly associated with CNS effects or with effects that could suggest an anticholinergic effect.
Adverse events reported after an intake of at least 5 times the recommended daily dose are: confusion, diarrhoea, dizziness, fatigue, headache, malaise, mydriasis, pruritus, restlessness, sedation, somnolence, stupor, tachycardia, tremor, and urinary retention.

Management

There is no known specific antidote to cetirizine.
Should overdose occur, symptomatic or supportive treatment is recommended. Gastric lavage should be considered following ingestion of a short occurrence.
Cetirizine is not effectively removed by dialysis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Piperazine derivatives, ATC code: R06A E07

Cetirizine, a human metabolite of hydroxyzine, is a potent and selective antagonist of peripheral H_1-receptors. *In vitro* receptor binding studies have shown no measurable affinity for other than H_1-receptors.

In addition to its anti-H_1 effect, cetirizine was shown to display anti-allergic activities: at a dose of 10 mg once or twice daily, it inhibits the late phase recruitment of eosinophils, in the skin and conjunctiva of atopic subjects submitted to allergen challenge.

Studies in healthy volunteers show that cetirizine, at doses of 5 and 10 mg strongly inhibits the wheal and flare reactions induced by very high concentrations of histamine into the skin, but the correlation with efficacy is not established.
In a 35-day study in children aged 5 to 12, no tolerance to the antihistaminic effect (suppression of wheal and flare) of cetirizine was found. When a treatment with cetirizine is stopped after repeated administration, the skin recovers its normal reactivity to histamine within 3 days.

In a six-week, placebo-controlled study of 186 patients with allergic rhinitis and concomitant mild to moderate asthma, cetirizine 10 mg once daily improved rhinitis symptoms and did not alter pulmonary function. This study supports the safety of administering cetirizine to allergic patients with mild to moderate asthma.

In a placebo-controlled study, cetirizine given at the high daily dose of 60 mg for seven days did not cause statistically significant prolongation of QT interval.

At the recommended dosage, cetirizine has demonstrated that it improves the quality of life of patients with perennial and seasonal allergic rhinitis.

5.2 Pharmacokinetic properties

The steady - state peak plasma concentrations is approximately 300 ng/ml and is achieved within 1.0 ± 0.5 h. No accumulation is observed for cetirizine following daily doses of 10 mg for 10 days. The distribution of pharmacokinetic parameters such as peak plasma concentration (C_{max}) and area under curve (AUC), is unimodal in human volunteers.
The extent of absorption of cetirizine is not reduced with food, although the rate of absorption is decreased. The extent of bioavailability is similar when cetirizine is given as solutions, capsules or tablets.

The apparent volume of distribution is 0.50 l/kg. Plasma protein binding of cetirizine is 93 ± 0.3 %. Cetirizine does not modify the protein binding of warfarin.

Cetirizine does not undergo extensive first pass metabolism. About two third of the dose are excreted unchanged in urine. The terminal half-life is approximately 10 hours.

Cetirizine exhibits linear kinetics over the range of 5 to 60 mg.

Special populations

Elderly: Following a single 10 mg oral dose, half-life increased by about 50 % and clearance decreased by 40 % in 16 elderly subjects compared to the normal subjects. The decrease in cetirizine clearance in these elderly volunteers appeared to be related to their decreased renal function.

Children, infants and toddlers: The half-life of cetirizine was about 6 hours in children of 6-12 years and 5 hours in children 2-6 years. In infants and toddlers aged 6 to 24 months, it is reduced to 3.1 hours

Renally impaired patients: The pharmacokinetics of the drug were similar in patients with mild impairment (creatinine clearance higher than 40 ml/min) and healthy volunteers. Patients with moderate renal impairment had a 3-fold increase in half-life and 70 % decrease in clearance compared to healthy volunteers.
Patients on hemodialysis (creatinine clearance less than 7 ml/min) given a single oral 10 mg dose of cetirizine had a 3-fold increase in half-life and a 70 % decrease in clearance compared to normals. Cetirizine was poorly cleared by haemodialysis. Dosing adjustment is necessary in patients with moderate or severe renal impairment (see section 4.2).

Hepatically impaired patients: Patients with chronic liver diseases (hepatocellular, cholestatic, and biliary cirrhosis) given 10 or 20 mg of cetirizine as a single dose had a 50 % increase in half-life along with a 40 % decrease in clearance compared to healthy subjects.
Dosing adjustment is only necessary in hepatically impaired patients if concomitant renal impairment is present.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Microcrystalline cellulose
- Lactose

- Colloidal anhydrous silica
- Magnesium stearate
- Opadry Y-1-7000
- Hydroxypropylmethylcellulose (E 464)
- Titanium dioxide (E 171)
- Macrogol 400

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

5 years

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Thermoformed transparent, colorless, physiologically inert PVC blister strip thermosealed by an aluminium foil covered by suitable lac; in a carton box.

Boxes of 1, 4, 5, 7, 10, 14, 15, 20, 21, 30, 40, 45, 50, 60, 90, or 100 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

[To be completed nationally]
{Name and address}
{tel}
{fax}
{e-mail}

8. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[To be completed nationally]

10. DATE OF REVISION OF THE TEXT

[To be completed nationally]

1. NAME OF THE MEDICINAL PRODUCT

Zyrtec 10 mg/ml oral drops, solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml of solution contains 10 mg cetirizine dihydrochloride, one drop of solution contains 0.5 mg cetirizine dihydrochloride

Excipients: - one ml of solution contains 1.35 mg methylparahydroxybenzoate
- one ml of solution contains 0.15 mg propylparahydroxybenzoate

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral drops, solution

Clear and colorless liquid

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

In adults and paediatric patient 2 year and above:

- Cetirizine is indicated for the relief of nasal and ocular symptoms of seasonal and perennial allergic rhinitis.
- Cetirizine is indicated for the relief of symptoms of chronic idiopathic urticaria.

4.2 Posology and method of administration

Children aged from 2 to 6 years: 2.5 mg twice daily (5 drops twice daily).

Children aged from 6 to 12 years: 5 mg twice daily (10 drops twice daily).

Adults and adolescents over 12 years of age: 10 mg once daily (20 drops).

The drops should be poured in a spoon or diluted in water, and taken orally.
If dilution is used, it should be considered, especially for administration to children, that the volume of water to which the drops are added, needs to be adapted according to the quantity of water the patient is able to swallow. The diluted solution should be taken immediately.

Elderly subjects: data do not suggest that the dose needs to be reduced in elderly subjects provided that the renal function is normal.

Patients with moderate to severe renal impairment: there are no data to document the efficacy/safety ratio in patients with renal impairment. Since cetirizine is mainly eliminated via renal route (see section 5.2.), in cases no alternative treatment can be used,the dosing intervals must be individualized according to renal function. Refer to the following table and adjust the dose as indicated. To use this dosing table, an estimate of the patient's creatinine clearance (CL_{cr}) in ml/min is needed. The CL_{cr} (ml/min) may be estimated from serum creatinine (mg/dl) determination using the following formula:

$$CL_{cr} = \frac{[140 - age(years)]\, x\, weight\,(kg)}{72\, x\, serum\, creatinine\,(mg/dl)} (x\, 0.85\ for\ women)$$

Dosing adjustments for adult patients with impaired renal function

Group	Creatinine clearance (ml/min)	Dosage and frequency
Normal	≥80	10 mg once daily
Mild	50 – 79	10 mg once daily
Moderate	30 – 49	5 mg once daily
Severe	30	5 mg once every 2 days
End-stage renal disease - Patients undergoing dialysis	10	Contra-indicated

In pediatric patients suffering from renal impairment, the dose will have to be adjusted on an individual basis taking into account the renal clearance of the patient, his age and his body weight.

Patients with hepatic impairment: no dose adjustment is needed in patients with solely hepatic impairment.

Patients with hepatic impairment and renal impairment: dose adjustment is recommended (see Patients with moderate to severe renal impairment above).

4.3 Contraindications

Hypersensitivity to the active substance, to any of the excipients, to hydroxyzine or to any piperazine derivatives.

Patients with severe renal impairment at less than 10 ml/min creatinine clearance.

4.4 Special warnings and precautions for use

At therapeutic doses, no clinically significant interactions have been demonstrated with alcohol (for a blood alcohol level of 0.5 g/l). Nevertheless, precaution is recommended if alcohol is taken concomitantly.

Caution in epileptic patients and patients at risk of convulsions is recommended.

The use of the product is not recommended in infants and toddlers aged less than 2 years.

Methyl parahydroxybenzoate and propyl parahydroxybenzoate may cause allergic reactions (possibly delayed).

4.5 Interaction with other medicinal products and other forms of interaction

Due to the pharmacokinetic, pharmacodynamic and tolerance profile of cetirizine, no interactions are expected with this antihistamine. Actually, neither pharmacodynamic nor significant pharmacokinetic interaction was reported in drug-drug interactions studies performed, notably with pseudoephedrine or theophylline (400 mg/day).

The extent of absorption of cetirizine is not reduced with food, although the rate of absorption is decreased.

4.6 Pregnancy and lactation

For cetirizine very rare clinical data on exposed pregnancies are available. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/fetal development, parturition or postnatal development. Caution should be exercised when prescribing to pregnant or breast feeding women because cetirizine passes into breast milk.

4.7 Effects on ability to drive and use machines

Objective measurements of driving ability, sleep latency and assembly line performance have not demonstrated any clinically relevant effects at the recommended dose of 10 mg.
Patients intending to drive, engaging in potentially hazardous activities or operating machinery should not exceed the recommended dose and should take their response to the medicinal product into account. In these sensitive patients, concurrent use with alcohol or other CNS depressants may cause additional reductions in alertness and impairment of performance.

4.8 Undesirable effects

Clinical studies have shown that cetirizine at the recommended dosage has minor undesirable effects on the CNS, including somnolence, fatigue, dizziness and headache. In some cases, paradoxical CNS stimulation has been reported.

Although cetirizine is a selective antagonist of peripheral H_1-receptors and is relatively free of anticholinergic activity, isolated cases of micturition difficulty, eye accommodation disorders and dry mouth have been reported.

Instances of abnormal hepatic function with elevated hepatic enzymes accompanied by elevated bilirubin have been reported. Mostly this resolves upon discontinuation of the treatment with cetirizine dihydrochloride.

Clinical trials

Double blind controlled clinical or pharmacoclinical trials comparing cetirizine to placebo or other antihistamines at the recommended dosage (10 mg daily for cetirizine), of which quantified safety data are available, included more than 3200 subjects exposed to cetirizine.
From this pooling, the following adverse events were reported for cetirizine 10 mg in the placebo-controlled trials at rates of 1.0 % or greater:

Adverse event (WHO-ART)	**Cetirizine 10 mg (n= 3260)**	**Placebo (n = 3061)**
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Dizziness	1.10 %	0.98 %
Headache	7.42 %	8.07 %
Gastro-intestinal system disorders		
Abdominal pain	0.98 %	1.08 %
Dry mouth	2.09 %	0.82 %
Nausea	1.07 %	1.14 %
Psychiatric disorders		
Somnolence	9.63 %	5.00 %
Respiratory system disorders		
Pharyngitis	1.29 %	1.34 %

Although statistically more common than under placebo, somnolence was mild to moderate in the majority of cases. Objective tests as demonstrated by other studies have demonstrated that usual daily activities are unaffected at the recommended daily dose in healthy young volunteers.

Adverse drug reactions at rates of 1 % or greater in children aged from 6 months to 12 years, included in placebo-controlled clinical or pharmacoclinical trials are:

Adverse drug reactions (WHO-ART)	**Cetirizine (n=1656)**	**Placebo (n =1294)**
Gastro-intestinal system disorders Diarrhoea	1.0 %	0.6 %
Psychiatric disorders Somnolence	1.8 %	1. 4 %
Respiratory system disorders Rhinitis	1.4 %	1.1 %
Body as a whole – general disorders Fatigue	1.0 %	0.3 %

Post-marketing experience

In addition to the adverse effects reported during clinical studies and listed above, isolated cases of the following adverse drug reactions have been reported in post-marketing experience. For these less frequently reported undesirable effects, the estimate d frequencies (uncommon: ≥1/1,000 to 1/100, rare: ≥1/10,000 to 1/1,000, very rare: 1/10,000) are made based on post-marketing experience.

Blood and lymphatic disorders:
Very rare: thrombocytopenia

Immune system disorders:
Rare: hypersensitivity
Very rare: anaphylactic shock

Psychiatric disorders:
Uncommon: agitation
Rare: aggression, confusion, depression, hallucination, insomnia
Very rare: tic

Nervous system disorders:
Uncommon: paraesthesia
Rare: convulsions, movements disorders
Very rare: dysgeusia, syncope, tremor, dystonia, dyskinesia

Eye disorders:
Very rare: accommodation disorder, blurred vision, oculogyration

Cardiac disorders:
Rare: tachycardia

Gastro-intestinal disorders:
Uncommon: diarrhoea

Hepatobiliary disorders:
Rare: hepatic function abnormal (increased transaminases, alkaline phosphatase, γ-GT and bilirubin)

Skin and subcutaneous tissue disorders:
Uncommon: pruritus, rash
Rare: urticaria
Very rare: angioneurotic oedema, fixed drug eruption

Renal and urinary disorders:
Very rare: dysuria, enuresis

General disorders and administration site conditions:
Uncommon: asthenia, malaise
Rare: oedema

Investigations:
Rare: weight increased

4.9 Overdose

Symptoms

Symptoms observed after an overdose of cetirizine are mainly associated with CNS effects or with effects that could suggest an anticholinergic effect.
Adverse events reported after an intake of at least 5 times the recommended daily dose are: confusion, diarrhoea, dizziness, fatigue, headache, malaise, mydriasis, pruritus, restlessness, sedation, somnolence, stupor, tachycardia, tremor, and urinary retention.

Management

There is no known specific antidote to cetirizine.
Should overdose occur, symptomatic or supportive treatment is recommended. Gastric lavage should be considered following ingestion of a short occurrence.
Cetirizine is not effectively removed by dialysis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Piperazine derivatives, ATC code: R06A E07

Cetirizine, a human metabolite of hydroxyzine, is a potent and selective antagonist of peripheral H_1-receptors. *In vitro* receptor binding studies have shown no measurable affinity for other than H_1-receptors.

In addition to its anti-H_1 effect, cetirizine was shown to display anti-allergic activities: at a dose of 10 mg once or twice daily, it inhibits the late phase recruitment of eosinophils, in the skin and conjunctiva of atopic subjects submitted to allergen challenge.

Studies in healthy volunteers show that cetirizine, at doses of 5 and 10 mg strongly inhibits the wheal and flare reactions induced by very high concentrations of histamine into the skin, but the correlation with efficacy is not established.
In a 35-day study in children aged 5 to 12, no tolerance to the antihistaminic effect (suppression of wheal and flare) of cetirizine was found. When a treatment with cetirizine is stopped after repeated administration, the skin recovers its normal reactivity to histamine within 3 days.

In a six-week, placebo-controlled study of 186 patients with allergic rhinitis and concomitant mild to moderate asthma, cetirizine 10 mg once daily improved rhinitis symptoms and did not alter pulmonary

function. This study supports the safety of administering cetirizine to allergic patients with mild to moderate asthma.

In a placebo-controlled study, cetirizine given at the high daily dose of 60 mg for seven days did not cause statistically significant prolongation of QT interval.

At the recommended dosage, cetirizine has demonstrated that it improves the quality of life of patients with perennial and seasonal allergic rhinitis.

5.2 Pharmacokinetic properties

The steady - state peak plasma concentrations is approximately 300 ng/ml and is achieved within 1.0 ± 0.5 h. No accumulation is observed for cetirizine following daily doses of 10 mg for 10 days. The distribution of pharmacokinetic parameters such as peak plasma concentration (C_{max}) and area under curve (AUC), is unimodal in human volunteers.
The extent of absorption of cetirizine is not reduced with food, although the rate of absorption is decreased. The extent of bioavailability is similar when cetirizine is given as solutions, capsules or tablets.

The apparent volume of distribution is 0.50 l/kg. Plasma protein binding of cetirizine is 93 ± 0.3 %. Cetirizine does not modify the protein binding of warfarin.

Cetirizine does not undergo extensive first pass metabolism. About two third of the dose are excreted unchanged in urine. The terminal half-life is approximately 10 hours.

Cetirizine exhibits linear kinetics over the range of 5 to 60 mg.

Special populations:

Elderly: Following a single 10 mg oral dose, half-life increased by about 50 % and clearance decreased by 40 % in 16 elderly subjects compared to the normal subjects. The decrease in cetirizine clearance in these elderly volunteers appeared to be related to their decreased renal function.

Children, infants and toddlers: The half-life of cetirizine was about 6 hours in children of 6-12 years and 5 hours in children 2-6 years. In infants and toddlers aged 6 to 24 months, it is reduced to 3.1 hours.

Renally impaired patients: The pharmacokinetics of the drug were similar in patients with mild impairment (creatinine clearance higher than 40 ml/min) and healthy volunteers. Patients with moderate renal impairment had a 3-fold increase in half-life and 70 % decrease in clearance compared to healthy volunteers.
Patients on hemodialysis (creatinine clearance less than 7 ml/min) given a single oral 10 mg dose of cetirizine had a 3-fold increase in half-life and a 70 % decrease in clearance compared to normals. Cetirizine was poorly cleared by haemodialysis. Dosing adjustment is necessary in patients with moderate or severe renal impairment (see section 4.2).

Hepatically impaired patients: Patients with chronic liver diseases (hepatocellular, cholestatic, and biliary cirrhosis) given 10 or 20 mg of cetirizine as a single dose had a 50 % increase in half-life along with a 40 % decrease in clearance compared to healthy subjects.
Dosing adjustment is only necessary in hepatically impaired patients if concomitant renal impairment is present.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Glycerol
- Propylene glycol
- Sodium saccharinate
- Methylparahydroxybenzoate (E 218)
- Propylparahydroxybenzoate (E 216)
- Sodium acetate
- Glacial acetic acid
- Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

5 years.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.6 Nature and contents of container

Amber glass bottle (type III) with 10, 15, 20, or 30 ml solution, fitted with a dropper insert in white low density polyethylene and closed with a white polypropylene child-resistant closure.

Not all pack sizes may be marketed.

6.7 Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

[To be completed nationally]
{Name and address}
{tel}
{fax}
{e-mail}

8. MARKETING AUTHORISATION NUMBER

[To be completed nationally]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[To be completed nationally]

10. DATE OF REVISION OF THE TEXT

[To be completed nationally]

1. NAME OF THE MEDICINAL PRODUCT

Zyrtec 1 mg/ml oral solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml of solution contains 1 mg cetirizine dihydrochloride

Excipients: - one ml of solution contains 450 mg sorbitol (solution at 70 %, non crystallizing)
- one ml of solution contains 1.35 mg methylparahydroxybenzoate
- one ml of solution contains 0.15 mg propylparahydroxybenzoate

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral solution

Clear and colorless liquid

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

In adults and children 2 year and above:

- Cetirizine is indicated for the relief of nasal and ocular symptoms of seasonal and perennial allergic rhinitis.
- Cetirizine is indicated for the relief of symptoms of chronic idiopathic urticaria.

4.2 Posology and method of administration

Children aged from 2 to 6 years: 2.5 mg twice daily (2.5 ml oral solution twice daily (a half spoon twice daily)).

Children aged from 6 to 12 years: 5 mg twice daily (5 ml oral solution bid (a full spoon twice daily).

Adults and adolescents over 12 years of age: 10 mg once daily (10 ml oral solution (2 full spoons)).

The solution can be swallowed as such.

Elderly subjects: data do not suggest that the dose needs to be reduced in elderly subjects provided that the renal function is normal.

Patients with moderate to severe renal impairment: there are no data to document the efficacy/safety ratio in patients with renal impairment. Since cetirizine is mainly eliminated via renal route (see section 5.2), in cases no alternative treatment can be used, the dosing intervals must be individualized according to renal function. Refer to the following table and adjust the dose as indicated. To use this dosing table, an estimate of the patient's creatinine clearance (CL_{cr}) in ml/min is needed. The CL_{cr} (ml/min) may be estimated from serum creatinine (mg/dl) determination using the following formula:

$$CL_{cr} = \frac{[140 - age(years)]\, x\, weight\,(kg)}{72\, x\, serum\, creatinine\,(mg/dl)} (x\, 0.85\ for\ women)$$

Dosing adjustments for adult patients with impaired renal function

Group	Creatinine clearance (ml/min)	Dosage and frequency
Normal	≥80	10 mg once daily
Mild	50 – 79	10 mg once daily
Moderate	30 – 49	5 mg once daily
Severe	30	5 mg once every 2 days
End-stage renal disease - Patients undergoing dialysis	10	Contra-indicated

In pediatric patients suffering from renal impairment, the dose will have to be adjusted on an individual basis taking into account the renal clearance of the patient, his age and his body weight.

Patients with hepatic impairment: no dose adjustment is needed in patients with solely hepatic impairment.

Patients with hepatic impairment and renal impairment: dose adjustment is recommended (see Patients with moderate to severe renal impairment above).

4.3 Contraindications

Hypersensitivity to the active substance, to any of the excipients, to hydroxyzine or to any piperazine derivatives.

Patients with severe renal impairment at less than 10 ml/min creatinine clearance.

Patients with rare hereditary problems of fructose intolerance should not take cetirizine 1 mg/ml oral solution**.**

4.4 Special warnings and precautions for use

At therapeutic doses, no clinically significant interactions have been demonstrated with alcohol (for a blood alcohol level of 0.5 g/L). Nevertheless, precaution is recommended if alcohol is taken concomitantly.

Caution in epileptic patients and patients at risk of convulsions is recommended.

The use of the product is not recommended in children aged less than 2 years.

Methyl parahydroxybenzoate and propyl parahydroxybenzoate may cause allergic reactions (possibly delayed).

4.5 Interaction with other medicinal products and other forms of interaction

Due to the pharmacokinetic, pharmacodynamic and tolerance profile of cetirizine, no interactions are expected with this antihistamine. Actually, neither pharmacodynamic nor significant pharmacokinetic interaction was reported in drug-drug interactions studies performed, notably with pseudoephedrine or theophylline (400 mg/day).

The extent of absorption of cetirizine is not reduced with food, although the rate of absorption is decreased.

4.6 Pregnancy and lactation

For cetirizine very rare clinical data on exposed pregnancies are available. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/fetal development, parturition or postnatal development. Caution should be exercised when prescribing to pregnant or breast feeding women because cetirizine passes into breast milk.

4.7 Effects on ability to drive and use machines

Objective measurements of driving ability, sleep latency and assembly line performance have not demonstrated any clinically relevant effects at the recommended dose of 10 mg.
Patients intending to drive, engaging in potentially hazardous activities or operating machinery should not exceed the recommended dose and should take their response to the medicinal product into account. In these sensitive patients, concurrent use with alcohol or other CNS depressants may cause additional reductions in alertness and impairment of performance.

4.8 Undesirable effects

Clinical studies have shown that cetirizine at the recommended dosage has minor undesirable effects on the CNS, including somnolence, fatigue, dizziness and headache. In some cases, paradoxical CNS stimulation has been reported.

Although cetirizine is a selective antagonist of peripheral H_1-receptors and is relatively free of anticholinergic activity, isolated cases of micturition difficulty, eye accommodation disorders and dry mouth have been reported.

Instances of abnormal hepatic function with elevated hepatic enzymes accompanied by elevated bilirubin have been reported. Mostly this resolves upon discontinuation of the treatment with cetirizine dihydrochloride.

Clinical trials

Double blind controlled clinical or pharmacoclinical trials comparing cetirizine to placebo or other antihistamines at the recommended dosage (10 mg daily for cetirizine), of which quantified safety data are available, included more than 3200 subjects exposed to cetirizine.
From this pooling, the following adverse events were reported for cetirizine 10 mg in the placebo-controlled trials at rates of 1.0 % or greater:

Adverse event (WHO-ART)	Cetirizine 10 mg (n= 3260)	Placebo (n = 3061)
Body as a whole – general disorders		
Fatigue	1.63 %	0.95 %
Central and peripheral nervous system disorders		
Dizziness	1.10 %	0.98 %
Headache	7.42 %	8.07 %
Gastro-intestinal system disorders		
Abdominal pain	0.98 %	1.08 %
Dry mouth	2.09 %	0.82 %
Nausea	1.07 %	1.14 %
Psychiatric disorders		
Somnolence	9.63 %	5.00 %
Respiratory system disorders		
Pharyngitis	1.29 %	1.34 %

Although statistically more common than under placebo, somnolence was mild to moderate in the majority of cases. Objective tests as demonstrated by other studies have demonstrated that usual daily activities are unaffected at the recommended daily dose in healthy young volunteers.

Adverse drug reactions at rates of 1 % or greater in children aged from 6 months to 12 years, included in placebo-controlled clinical or pharmacoclinical trials are:

Adverse drug reactions (WHO-ART)	Cetirizine (n=1656)	Placebo (n =1294)
Gastro-intestinal system disorders		
Diarrhoea	1.0 %	0.6 %
Psychiatric disorders		
Somnolence	1.8 %	1. 4 %
Respiratory system disorders		
Rhinitis	1.4 %	1.1 %
Body as a whole – general disorders		
Fatigue	1.0 %	0.3 %

Post-marketing experience

In addition to the adverse effects reported during clinical studies and listed above, isolated cases of the following adverse drug reactions have been reported in post-marketing experience. For these less frequently reported undesirable effects, the estimated frequencies (uncommon: ≥1/1,000 to 1/100, rare: ≥1/10,000 to 1/1,000, very rare: 1/10,000) are made based on post-marketing experience.

Blood and lymphatic disorders:
Very rare: thrombocytopenia

Immune system disorders:
Rare: hypersensitivity
Very rare: anaphylactic shock

Psychiatric disorders:
Uncommon: agitation
Rare: aggression, confusion, depression, hallucination, insomnia
Very rare: tic

Nervous system disorders:
Uncommon: paraesthesia

Rare: convulsions, movements disorders
Very rare: dysgeusia, syncope, tremor, dystonia, dyskinesia

Eye disorders:
Very rare: accommodation disorder, blurred vision, oculogyration

Cardiac disorders:
Rare: tachycardia

Gastro-intestinal disorders:
Uncommon: diarrhoea

Hepatobiliary disorders:
Rare: hepatic function abnormal (increased transaminases, alkaline phosphatase, γ-GT and bilirubin)

Skin and subcutaneous tissue disorders:
Uncommon: pruritus, rash
Rare: urticaria
Very rare: angioneurotic oedema, fixed drug eruption

Renal and urinary disorders:
Very rare: dysuria, enuresis

General disorders and administration site conditions:
Uncommon: asthenia, malaise
Rare: oedema

Investigations:
Rare: weight increased

4.9 Overdose

Symptoms

Symptoms observed after an overdose of cetirizine are mainly associated with CNS effects or with effects that could suggest an anticholinergic effect.
Adverse events reported after an intake of at least 5 times the recommended daily dose are: confusion, diarrhoea, dizziness, fatigue, headache, malaise, mydriasis, pruritus, restlessness, sedation, somnolence, stupor, tachycardia, tremor, and urinary retention.

Management

There is no known specific antidote to cetirizine.
Should overdose occur, symptomatic or supportive treatment is recommended. Gastric lavage should be considered following ingestion of a short occurrence.
Cetirizine is not effectively removed by dialysis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Piperazine derivatives, ATC code: R06A E07

Cetirizine, a human metabolite of hydroxyzine, is a potent and selective antagonist of peripheral H_1-receptors. *In vitro* receptor binding studies have shown no measurable affinity for other than H_1-receptors.

In addition to its anti-H_1 effect, cetirizine was shown to display anti-allergic activities: at a dose of 10 mg once or twice daily, it inhibits the late phase recruitment of eosinophils, in the skin and conjunctiva of atopic subjects submitted to allergen challenge.

Studies in healthy volunteers show that cetirizine, at doses of 5 and 10 mg strongly inhibits the wheal and flare reactions induced by very high concentrations of histamine into the skin, but the correlation with efficacy is not established.
In a 35-day study in children aged 5 to 12, no tolerance to the antihistaminic effect (suppression of wheal and flare) of cetirizine was found. When a treatment with cetirizine is stopped after repeated administration, the skin recovers its normal reactivity to histamine within 3 days.

In a six-week, placebo-controlled study of 186 patients with allergic rhinitis and concomitant mild to moderate asthma, cetirizine 10 mg once daily improved rhinitis symptoms and did not alter pulmonary function. This study supports the safety of administering cetirizine to allergic patients with mild to moderate asthma.

In a placebo-controlled study, cetirizine given at the high daily dose of 60 mg for seven days did not cause statistically significant prolongation of QT interval.

At the recommended dosage, cetirizine has demonstrated that it improves the quality of life of patients with perennial and seasonal allergic rhinitis.

5.2 Pharmacokinetic properties

The steady - state peak plasma concentrations is approximately 300 ng/ml and is achieved within 1.0 ± 0.5 h. No accumulation is observed for cetirizine following daily doses of 10 mg for 10 days. The distribution of pharmacokinetic parameters such as peak plasma concentration (C_{max}) and area under curve (AUC), is unimodal in human volunteers.
The extent of absorption of cetirizine is not reduced with food, although the rate of absorption is decreased. The extent of bioavailability is similar when cetirizine is given as solutions, capsules or tablets.

The apparent volume of distribution is 0.50 l/kg. Plasma protein binding of cetirizine is 93 ± 0.3 %. Cetirizine does not modify the protein binding of warfarin.

Cetirizine does not undergo extensive first pass metabolism. About two third of the dose are excreted unchanged in urine. The terminal half-life is approximately 10 hours.

Cetirizine exhibits linear kinetics over the range of 5 to 60 mg.

Special populations

Elderly: Following a single 10 mg oral dose, half-life increased by about 50 % and clearance decreased by 40 % in 16 elderly subjects compared to the normal subjects. The decrease in cetirizine clearance in these elderly volunteers appeared to be related to their decreased renal function.

Children, infants and toddlers: The half-life of cetirizine was about 6 hours in children of 6-12 years and 5 hours in children 2-6 years. In infants and toddlers aged 6 to 24 months, it is reduced to 3.1 hours.

Renally impaired patients: The pharmacokinetics of the drug were similar in patients with mild impairment (creatinine clearance higher than 40 ml/min) and healthy volunteers. Patients with

moderate renal impairment had a 3-fold increase in half-life and 70 % decrease in clearance compared to healthy volunteers.
Patients on hemodialysis (creatinine clearance less than 7 ml/min) given a single oral 10 mg dose of cetirizine had a 3-fold increase in half-life and a 70 % decrease in clearance compared to normals. Cetirizine was poorly cleared by haemodialysis. Dosing adjustment is necessary in patients with moderate or severe renal impairment (see section 4.2).

Hepatically impaired patients: Patients with chronic liver diseases (hepatocellular, cholestatic, and biliary cirrhosis) given 10 or 20 mg of cetirizine as a single dose had a 50 % increase in half-life along with a 40 % decrease in clearance compared to healthy subjects.
Dosing adjustment is only necessary in hepatically impaired patients if concomitant renal impairment is present.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Sorbitol solution at 70 % (non crystallizing) (E420)
- Glycerol
- Propylene glycol
- Sodium saccharinate
- Methylparahydroxybenzoate (E 218)
- Propylparahydroxybenzoate (E 216)
- Banana flavor 54.330/A (Firmenich)
- Sodium acetate
- Glacial acetic acid
- Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

5 years

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions

6.5 Nature and contents of container

Amber glass bottle (type III) of 60, 75, 100, 125, 150, or 200 ml, closed with a white polypropylene child-resistant closure.

A 5ml Dosing spoon with a line at 2.5 ml is provided with the bottle.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements

7. MARKETING AUTHORISATION HOLDER

[To be completed nationally]
{Name and address}
{tel}
{fax}
{e-mail}

8. MARKETING AUTHORISATION NUMBER

[To be completed nationally]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[To be completed nationally]

10. DATE OF REVISION OF THE TEXT

[To be completed nationally]

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON BOX

1. NAME OF THE MEDICINAL PRODUCT

Zyrtec 10 mg film-coated tablets

Cetirizine dihydrochloride

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 10 mg of cetirizine dihydrochloride

3. LIST OF EXCIPIENTS

Also contains lactose. Read the package leaflet before use.

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated tablets
1 tablet
4 tablets
5 tablets
7 tablets
10 tablets
14 tablets
15 tablets
20 tablets
21 tablets
30 tablets
40 tablets
45 tablets
50 tablets
60 tablets
90 tablets
100 tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

Exp:

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]
{Name and address}
{tel}
{fax}
{e-mail}

12. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

13. BATCH NUMBER

Batch:

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

[To be completed nationally]

16. INFORMATION IN BRAILLE

Zyrtec 10 mg tablets

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

PVC/ALUMINIUM BLISTERS

1. NAME OF THE MEDICINAL PRODUCT

Zyrtec 10 mg film-coated tablets

Cetirizine dihydrochloride

2. NAME OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]

3. EXPIRY DATE

Exp:

4. BATCH NUMBER

Batch:

5. OTHER

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

CARTON BOX AND BOTTLES

1. NAME OF THE MEDICINAL PRODUCT

Zyrtec 10 mg/ml oral drops, solution

Cetirizine dihydrochloride

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One ml of solution contains 10 mg of cetirizine dihydrochloride, one drop of solution contains 0.5 mg cetirizine dihydrochloride

3. LIST OF EXCIPIENTS

Contains methylparahydroxybenzoate (E 218) and propylparahydroxybenzoate (E 216), among other substances. Read the package leaflet before use.

4. PHARMACEUTICAL FORM AND CONTENTS

Oral drops, solution
Bottle of 10 ml
Bottle of 15 ml
Bottle of 20 ml
Bottle of 30 ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

Exp:

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]
{Name and address}
{tel}
{fax}
{e-mail}

12. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

13. BATCH NUMBER

Batch:

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

[To be completed nationally]

16. INFORMATION IN BRAILLE

Zyrtec 10 mg/ml oral drops

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

CARTON BOX AND BOTTLE

1. NAME OF THE MEDICINAL PRODUCT

Zyrtec 1 mg/ml oral solution

Cetirizine dihydrochloride

2. STATEMENT OF ACTIVE SUBSTANCE(S)

1 ml solution contain 1 mg of cetirizine dihydrochloride

3. LIST OF EXCIPIENTS

Contains methylparahydroxybenzoate (E 218), propylparahydroxybenzoate (E 216), sorbitol (E 420), among other substances. Read the package leaflet before use.

4. PHARMACEUTICAL FORM AND CONTENTS

Oral solution
Bottle of 60 ml
Bottle of 75 ml
Bottle of 100 ml
Bottle of 125 ml
Bottle of 150 ml
Bottle of 200 ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

Exp:

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]
{Name and address}
{tel}
{fax}
{e-mail}

12. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

13. BATCH NUMBER

Batch:

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

[To be completed nationally]

16. INFORMATION IN BRAILLE

Zyrtec 1 mg/ml oral solution

PACKAGE LEAFLET

PACKAGE LEAFLET
For medicinal products available on prescription

PACKAGE LEAFLET: INFORMATION FOR THE USER

Zyrtec and associated names (see Annex I) 10 mg film-coated tablets

Cetirizine dihydrochloride

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT Zyrtec IS AND WHAT IT IS USED FOR

Cetirizine dihydrochloride is the active ingredient of Zyrtec. Zyrtec is an antiallergic medication.

In adults and children aged 6 year and above, Zyrtec is indicated
- for the relief of nasal and ocular symptoms of seasonal and perennial allergic rhinitis.
- for the relief of chronic nettle rash (chronic idiopathic urticaria).

2. BEFORE YOU TAKE ZYRTEC

Do not take Zyrtec
- if you have a severe kidney disease (severe renal failure with creatinine clearance below 10 ml/min);
- if you are known to be hypersensitive to the active substance of Zyrtec, to any of its excipients (other constituents), to hydroxyzine or to piperazine derivatives (closely related active substances of other medicines).

You should not take Zyrtec 10 mg tablets*:*
- if you have hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption

Take special care with Zyrtec
If you are a patient with renal insufficiency, please ask your doctor for advice; if necessary, you will take a lower dose. The new dose will be determined by your doctor.

If you are an epileptic patient or a patient at risk of convulsions, you should ask your doctor for advice.

No interactions suceptible to have a noticeable impact have been observed between alcohol (at the blood level of 0.5 per mille corresponding to one glass of wine) and cetirizine used at the normal doses. However, as it is the case with all antihistamines, it is recommended to avoid concurrent consumption of alcohol.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Due to the profile of cetirizine, no interactions with other drugs are expected

Taking Zyrtec with food and drink
Food does not affect noticeabily the absorbtion of cetirizine.

Pregnancy and breast-feeding
Ask your doctor for advice before taking any medicine.

As with other drugs, use of Zyrtec should be avoided in pregnant women. Accidental use of the drug by a pregnant woman should not produce any harmful effects on the foetus. Nevertheless, the administration of the medicine should be discontinued.

You should not take Zyrtec during breast feeding because cetirizine passes into breast milk.

Driving and using machines
Clinical studies have produced no evidence of impaired attention, alertness and driving capabilities after taking Zyrtec at the recommended dose.
If you are intending to drive, engage in potentially hazardous activities or operate machinery, you should not exceed the recommended dose. You should closely observe your response to the drug.
If you are a sensitive patient, you may find that the simultaneous use of alcohol or other nervous depressant agents may additionally affect your attention and ability to react.

Important information about some of the ingredients of Zyrtec
Zyrtec film-coated tablets contains lactose; if you have been told by your doctor that you have an intolerance to some sugars, please contact your doctor before taking this medicinal product.

3. HOW TO TAKE ZYRTEC

How and when should you take Zyrtec?
These guidelines apply unless your doctor has given you different instructions on how to use Zyrtec. Please follow these instructions, otherwise Zyrtec may not be fully effective.

Tablets need to be swallowed with a glass of liquid.

Adults and adolescents above 12 years old:
10 mg once daily as 1 tablet.

Children between 6 and 12 years old:
5 mg twice daily as a half tablet twice daily.

Patients with moderate to severe renal impairment
Patients with moderate renal impairment are recommended to take 5 mg once daily.

If you feel that the effect of Zyrtec is too weak or too strong, please consult your doctor.

Duration of treatment:
The duration of treatment depends on the type, duration and course of your complaints and is determined by your doctor.

If you take more Zyrtec than you should

If you think you have taken an overdose of Zyrtec please inform your doctor.
Your doctor will then decide what measures, if any, should be taken.

After an overdose, the side effects described below may occur with increased intensity. Adverse effects such as confusion, diarrhoea, dizziness, tiredness, headache, ailing, dilating of pupil, itching, restlessness, sedation, somnolence, stupor, abnormal rapid heart rate, tremors and urinary retention have been reported.

If you forget to take Zyrtec
Do not take a double dose to make up for forgotten dose.

If you stop taking Zyrtec
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Zyrtec can cause side effects, although not everybody gets them.

Following side effects have been reported in post marketing experience. The frequencies are defined as such: (common: 1 patient out of 100 to 1 out of 10, uncommon: 1 out of 1,000 to 1 out of 100, rare: 1 out of 10,000 to 1 out of 1,000, very rare: less than 1 out of 10,000).

- Blood and lymphatic disorders:
  very rare: thrombocytopenia (low levels of blood platelets)

- Body as a whole:
  common: fatigue

- Cardiac disorders:
  rare: tachycardia (heart beating too fast)

- Eye disorders:
  very rare: accommodation disorder, blurred vision, oculogyration (eyes having uncontrolled circular movements)

- Gastro-intestinal disorders:
  common: dry mouth, nausea, diarrhoea
  uncommon:, abdominal pain

- General disorders and administration site conditions:
  uncommon: asthenia (extreme fatigue), malaise
  rare: oedema (swelling)

- Immune system disorders:
  rare: allergic reactions, some severe (very rare)

- Hepatobiliary disorders:
  rare: liver function abnormal

- Investigations:
  rare: weight increased

- Nervous system disorders:
  common: dizziness, headache
  uncommon: paresthesia (abnormal feelings of the skin)

rare: convulsions, movements disorders
very rare: syncope, tremor, dysgeusia (altered taste)

- Psychiatric disorders:
  common: somnolence
  uncommon: agitation
  rare: aggression, confusion, depression, hallucination, insomnia
  very rare: tic

- Renal and urinary disorders:
  very rare: abnormal elimination of urine

- Respiratory system disorders:
  common: pharyngitis, rhinitis

- Skin and subcutaneous tissue disorders:
  uncommon: pruritus, rash
  rare: urticaria
  very rare: oedema, fixed drug eruption
-

If you develop one of the side effects described above, please inform your doctor. At the first signs of a hypersensitivity reaction, stop taking Zyrtec. **Your doctor will then assess the severity and decide on any further measures that may be necessary.**
If you think you have any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE ZYRTEC

Keep out of the reach and sight of children.

Do not use Zyrtec after the expiry date which is stated on the box and blister.

This medicine does not require any special storage conditions.

6. FURTHER INFORMATION

What Zyrtec contains
- The active substance of Zyrtec is cetirizine dihydrochloride. One film-coated tablet contains 10 mg cetirizine dihydrochloride.
- The other ingredients are microcrystalline cellulose, lactose, macrogol 400, magnesium stearate, hypromellose, colloidal silicon dioxide, titanium dioxide (E 171).

What Zyrtec looks like and contents of the pack
White, oblong, film-coated tablet, with breakline and Y-Y logo

Pack with 1, 4, 5, 7, 10, 14, 15, 20, 21, 30, 40, 45, 50, 60, 90, or 100 tablets.

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]
{Name and address}

{tel}
{fax}
{e-mail}

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria: Zyrtec 10 mg -Filmtabletten
Belgium: Reactine, Cetirizine-UCB, Zyrtec
Bulgaria: Zyrtec
Cyprus: Zyrtec
Czech Republic: Zyrtec
Denmark: Benaday, Zyrtec
Estonia: Zyrtec
Finland: Benaday, Zyrtec
France: Reactine, Virlix, Cetirizine UCB 10mg, Zyrtec, Actifed Allergie cetirizine 10mg, Zyrtecset
Germany: Zyrtec, Zyrtec P, Reactine
Greece: Ziptek
Hungary: Zyrtec filmtabletta, Zyrtec start filmtabletta
Ireland: Zirtek tablets
Italy: Formistin, Virlix, Zirtec 10 mg compresse rivestite con film
Latvia: Zyrtec
Lithuania: Zyrtec
Luxembourg: Reactine, Zyrtec, Cetirizine-UCB
Malta: Zyrtec
Netherlands: Reactine, Zyrtec
Norway: Reactine, Zyrtec
Poland: Reactine, Virlix, Zyrtec, Zyrtec UCB
Portugal: Zyrtec, Virlix
Romania: Zyrtec
Slovak Republic: Zyrtec tbl flm 10mg
Slovenia: Zyrtec10 mg filmsko oblozene tablete
Spain: Alerlisin, Virlix, Reactine, Zyrtec comprimidos recubiertos con pelicula, Alerrid 10 mg comprimidos recubiertos con pelicula
Sweden: Alerid, Zyrlex
United Kingdom: Benadryl one a day, Benadryl one a day relief, Zirtek allergy relief tablets

This leaflet was last approved in {MM/YYYY}.

[To be completed nationally]

PACKAGE LEAFLET
For medicinal products available without a prescription

PACKAGE LEAFLET: INFORMATION FOR THE USER

Zyrtec and associated names (see Annex I) 10 mg film-coated tablets

Cetirizine dihydrochloride

Read all of this leaflet carefully because it contains important information for you.
This medicine is available without prescription. However, you still need to use Zyrtec carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 3 days.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT Zyrtec IS AND WHAT IT IS USED FOR

Cetirizine dihydrochloride is the active ingredient of Zyrtec.
Zyrtec is an antiallergic medication.

In adults and children aged 6 year and above, Zyrtec is indicated
- for the relief of nasal and ocular symptoms of seasonal and perennial allergic rhinitis.
- for the relief of chronic nettle rash (chronic idiopathic urticaria).

2. BEFORE YOU TAKE ZYRTEC

Do not take Zyrtec
- if you have a severe kidney disease (severe renal failure with creatinine clearance below 10 ml/min);
- if you are known to be hypersensitive to the active substance of Zyrtec, to any of its excipients (other constituents), to hydroxyzine or to piperazine derivatives (closely related active substances of other medicines).

You should not take Zyrtec 10 mg tablets*:*
- if you have hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption

Take special care with Zyrtec
If you are a patient with renal insufficiency, please ask your doctor for advice; if necessary, you will take a lower dose. The new dose will be determined by your doctor.

If you are an epileptic patient or a patient at risk of convulsions, you should ask your doctor for advice.

No interactions suceptible to have a noticeable impact have been observed between alcohol (at the blood level of 0.5 per mille corresponding to one glass of wine) and cetirizine used at the normal

doses. However, as it is the case with all antihistamines, it is recommended to avoid concurrent consumption of alcohol.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Due to the profile of cetirizine, no interactions with other drugs are expected

Taking Zyrtec with food and drink
Food does not affect noticeabily the absorbtion of cetirizine.

Pregnancy and breast-feeding
Ask your doctor for advice before taking any medicine.

As with other drugs, use of Zyrtec should be avoided in pregnant women. Accidental use of the drug by a pregnant woman should not produce any harmful effects on the foetus. Nevertheless, the administration of the medicine should be discontinued.

You should not take Zyrtec during breast feeding because cetirizine passes into breast milk.

Driving and using machines
Clinical studies have produced no evidence of impaired attention, alertness and driving capabilities after taking Zyrtec at the recommended dose.
If you are intending to drive, engage in potentially hazardous activities or operate machinery, you should not exceed the recommended dose. You should closely observe your response to the drug.
If you are a sensitive patient, you may find that the simultaneous use of alcohol or other nervous depressant agents may additionally affect your attention and ability to react.

Important information about some of the ingredients of Zyrtec
Zyrtec film-coated tablets contain lactose; if you have been told by your doctor that you have an intolerance to some sugars, please contact your doctor before taking this medicinal product.

3. HOW TO TAKE ZYRTEC

How and when should you take Zyrtec?
These guidelines apply unless your doctor has given you different instructions on how to use Zyrtec. Please follow these instructions, otherwise Zyrtec may not be fully effective.

Tablets need to be swallowed with a glass of liquid.

Adults and adolescents above 12 years old:
10 mg once daily as 1 tablet.

Children between 6 and 12 years old:
5 mg twice daily as a half tablet twice daily.

Patients with moderate to severe renal impairment
Patients with moderate renal impairment are recommended to take 5 mg once daily.

If you feel that the effect of Zyrtec is too weak or too strong, please consult your doctor.

Duration of treatment:
The duration of treatment depends on the type, duration and course of your complaints and is determined by your doctor.

If you take more Zyrtec than you should
If you think you have taken an overdose of Zyrtec please inform your doctor.
Your doctor will then decide what measures, if any, should be taken.

After an overdose, the side effects described below may occur with increased intensity. Adverse effects such as confusion, diarrhoea, dizziness, tiredness, headache, ailing, dilating of pupil, itching, restlessness, sedation, somnolence, stupor, abnormal rapid heart rate, tremors and urinary retention have been reported.

If you forget to take Zyrtec
Do not take a double dose to make up for forgotten dose.

If you stop taking Zyrtec
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Zyrtec can cause side effects, although not everybody gets them.

Following side effects have been reported in post marketing experience. The frequencies are defined as such: (common: 1 patient out of 100 to 1 out of 10, uncommon: 1 out of 1,000 to 1 out of 100, rare: 1 out of 10,000 to 1 out of 1,000, very rare: less than 1 out of 10,000).

- Blood and lymphatic disorders:
  very rare: thrombocytopenia (low levels of blood platelets)

- Body as a whole:
  common: fatigue

- Cardiac disorders:
  rare: tachycardia (heart beating too fast)

- Eye disorders:
  very rare: accommodation disorder, blurred vision, oculogyration (eyes having uncontrolled circular movements)

- Gastro-intestinal disorders:
  common: dry mouth, nausea, diarrhoea
  uncommon:, abdominal pain

- General disorders and administration site conditions:
  uncommon: asthenia (extreme fatigue), malaise
  rare: oedema (swelling)

- Immune system disorders:
  rare: allergic reactions, some severe (very rare)

- Hepatobiliary disorders:
  rare: liver function abnormal

- Investigations:
  rare: weight increased

- Nervous system disorders:

common: dizziness, headache
uncommon: paresthesia (abnormal feelings of the skin)
rare: convulsions, movements disorders
very rare: syncope, tremor, dysgeusia (altered taste)

- Psychiatric disorders:
  common: somnolence
  uncommon: agitation
  rare: aggression, confusion, depression, hallucination, insomnia
  very rare: tic

- Renal and urinary disorders:
  very rare: abnormal elimination of urine

- Respiratory system disorders:
  common: pharyngitis, rhinitis

- Skin and subcutaneous tissue disorders:
  uncommon: pruritus, rash
  rare: urticaria
  very rare: oedema, fixed drug eruption
-

If you develop one of the side effects described above, please inform your doctor. At the first signs of a hypersensitivity reaction, stop taking Zyrtec. Your doctor will then assess the severity and decide on any further measures that may be necessary.
If you think you have any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE ZYRTEC

Keep out of the reach and sight of children.

Do not use Zyrtec after the expiry date which is stated on the box and blister.

This medicine does not require any special storage conditions.

6. FURTHER INFORMATION

What Zyrtec contains
- The active substance of Zyrtec is cetirizine dihydrochloride. One film-coated tablet contains 10 mg cetirizine dihydrochloride.
- The other ingredients are microcrystalline cellulose, lactose, macrogol 400, magnesium stearate, hypromellose, colloidal silicon dioxide, titanium dioxide (E 171).

What Zyrtec looks like and contents of the pack
White, oblong, film-coated tablet, with breakline and Y-Y logo

Pack with 1, 4, 5, 7, 10, 14, 15, 20, 21, 30, 40, 45, 50, 60, 90, or 100 tablets.

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]
{Name and address}
{tel}
{fax}
{e-mail}

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria: Zyrtec 10 mg -Filmtabletten
Belgium: Reactine, Cetirizine-UCB, Zyrtec
Bulgaria: Zyrtec
Cyprus: Zyrtec
Czech Republic: Zyrtec
Denmark: Benaday, Zyrtec
Estonia: Zyrtec
Finland: Benaday, Zyrtec
France: Reactine, Virlix, Cetirizine UCB 10mg, Zyrtec, Actifed Allergie cetirizine 10mg, Zyrtecset
Germany: Zyrtec, Zyrtec P, Reactine
Greece: Ziptek
Hungary: Zyrtec filmtabletta, Zyrtec start filmtabletta
Ireland: Zirtek tablets
Italy: Formistin, Virlix, Zirtec 10 mg compresse rivestite con film
Latvia: Zyrtec
Lithuania: Zyrtec
Luxembourg: Reactine, Zyrtec, Cetirizine-UCB
Malta: Zyrtec
Netherlands: Reactine, Zyrtec
Norway: Reactine, Zyrtec
Poland: Reactine, Virlix, Zyrtec, Zyrtec UCB
Portugal: Zyrtec, Virlix
Romania: Zyrtec
Slovak Republic: Zyrtec tbl flm 10mg
Slovenia: Zyrtec10 mg filmsko oblozene tablete
Spain: Alerlisin, Virlix, Reactine, Zyrtec comprimidos recubiertos con pelicula, Alerrid 10 mg comprimidos recubiertos con pelicula
Sweden: Alerid, Zyrlex
United Kingdom: Benadryl one a day, Benadryl one a day relief, Zirtek allergy relief tablets

This leaflet was last approved in {MM/YYYY}.
[To be completed nationally]

PACKAGE LEAFLET
For medicinal products available on prescription

PACKAGE LEAFLET: INFORMATION FOR THE USER

Zyrtec and associated names (see Annex I) 10 mg/ml oral drops, solution

Cetirizine dihydrochloride

Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT Zyrtec IS AND WHAT IT IS USED FOR

Cetirizine dihydrochloride is the active ingredient of Zyrtec.
Zyrtec is an antiallergic medication.

In adults and paediatric patients aged 2 year and above, Zyrtec is indicated
- for the relief of nasal and ocular symptoms of seasonal and perennial allergic rhinitis.
- for the relief of chronic nettle rash (chronic idiopathic urticaria).

2. BEFORE YOU TAKE ZYRTEC

Do not take Zyrtec
- if you have a severe kidney disease (severe renal failure with creatinine clearance below 10 ml/min);
- if you are known to be hypersensitive to the active substance of Zyrtec, to any of its excipients (other constituents), to hydroxyzine or to any piperazine derivatives (closely related active substances of other medicines).

Take special care with Zyrtec
If you are a patient with renal insufficiency. Please ask your doctor for advice; if necessary, you will take a lower dose. The new dose will be determined by your Doctor.

If you are an epileptic patient or a patient at risk of convulsions, you should ask your doctor for advice.

No interactions suceptible to have a noticeable impact have been observed between alcohol (at the blood level of 0.5 per mille corresponding to one glass of wine) and cetirizine used at the normal doses. However, as it is the case with all antihistamines, it is recommended to avoid concurrent consumption of alcohol.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken other medicine, including medicines obtained without a prescription.

Due to the profile of cetirizine, no interactions with other drugs are expected.

Taking Zyrtec with food and drink
Food does not affect noticeabily the absorption of cetirizine.

Pregnancy and breast-feeding
Ask your doctor for advice before taking any medicine.

As with other drugs, use of Zyrtec should be avoided in pregnant women. Accidental use of the drug by a pregnant women should not produce any harmful effects on the foetus. Nevertheless, the administration of the medicine should be discontinued.

You should not take Zyrtec during breast feeding because cetirizine passes into breast milk.

Driving and using machines
Clinical studies have produced no evidence of impaired attention, alertness and driving capabilities after taking Zyrtec at the recommended dose.
If you are intending to drive, engage in potentially hazardous activities or operate machinery, you should not exceed the recommended dose. You should closely observe your response to the drug.
If you are a sensitive patient, you may find that the simultaneous use of alcohol or other nervous depressant agents may additionally affect your attention and ability to react.

Important information about some of the ingredients of Zyrtec
Zyrtec oral drops solution contain methyl (4-hydroxybenzoate) E 218 propyl (4-hydroxybenzoate) E 216 that may cause allergic reactions (possibly delayed).

3. HOW TO TAKE ZYRTEC

How and when should you take Zyrtec?
These guidelines apply unless your Doctor has given you different instructions on how to use Zyrtec. Please follow these instructions, otherwise Zyrtec may not be fully effective.

Adults and adolescents above 12 years old:
10 mg once daily as 20 drops

Children between 6 and 12 years old:
5 mg twice daily as 10 drops twice daily.

Children between 2 and 6 years old
2.5 mg twice daily administered as 5 drops twice daily

Patients with moderate to severe renal impairment
Patients with moderate renal impairment are recommended to take 5 mg as 10 drops once daily.

If you feel that the effect of Zyrtec is too weak or too strong, please consult your doctor.

Duration of treatment
The duration of treatment depends on the type, duration and course of your complaints and is determined by your doctor.

If you take more Zyrtec than you should

If you think you have taken an overdose of Zyrtec please inform your doctor.
Your doctor will then decide what measures, if any, should be taken.

After an overdose, the side effects described below may occur with increased intensity. Adverse effects such as confusion, diarrhoea, dizziness, tiredness, headache, ailing, dilating of pupil, itching, restlessness, sedation, somnolence, stupor, abnormal rapid heart rate, tremors and urinary retention have been reported.

If you forget to take Zyrtec
Do not take a double dose to make up for forgotten dose

If you stop taking Zyrtec
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Zyrtec can cause side effects, although not everybody gets them.

Following side effects have been reported in post marketing experience. The frequencies are defined as such: (common: 1 patient out of 100 to 1 out of 10, uncommon: 1 out of 1,000 to 1 out of 100, rare: 1 out of 10,000 to 1 out of 1,000, very rare: less than 1 out of 10,000).

- Blood and lymphatic disorders:
  very rare: thrombocytopenia (low levels of blood platelets)

- Body as a whole:
  common: fatigue

- Cardiac disorders:
  rare: tachycardia (heart beating too fast)

- Eye disorders:
  very rare: accommodation disorder, blurred vision, oculogyration (eyes having uncontrolled circular movements)

- Gastro-intestinal disorders:
  common: dry mouth, nausea, diarrhoea
  uncommon:, abdominal pain,

- General disorders and administration site conditions:
  uncommon: asthenia (extreme fatigue), malaise,
  rare: oedema (swelling)

- Immune system disorders:
  rare: allergic reactions, some severe (very rare)

- Hepatobiliary disorders:
  rare: liver function abnormal

- Investigations:
  rare: weight increased

- Nervous system disorders:
  common: dizziness, headache
  uncommon: paresthesia (abnormal feelings of the skin),

rare: convulsions, movements disorders
very rare: syncope, tremor, dysgeusia (altered taste)

- Psychiatric disorders:
common: somnolence
uncommon: agitation
rare: aggression, confusion, depression, hallucination, insomnia
very rare: tic

- Renal and urinary disorders:
very rare: abnormal elimination of urine

- Respiratory system disorders:
common: pharyngitis, rhinitis

- Skin and subcutaneous tissue disorders:
uncommon: pruritus, rash,
rare: urticaria,
very rare: oedema, fixed drug eruption

If you develop one of the side effects described above, please inform your doctor. At the first signs of a hypersensitivity reaction, stop taking Zyrtec. **Your doctor will then assess the severity and decide on any further measures that may be necessary.**
If you think you have any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE ZYRTEC

Keep out of the reach and sight of children.

Do not use Zyrtec after the expiry date which is stated on the box and bottle.

This medicine does not require any special storage conditions.

6. FURTHER INFORMATION

What Zyrtec contains
- The active substance of Zyrtec is cetirizine dihydrochloride. One ml (equals to 20 drops) contains 10 mg of cetirizine dihydrochloride. One drop contains 0.5 mg of cetirizine dihydrochloride.
- The other ingredients are glycerol, propylène glycol, saccharine sodium, methyl (4-hydroxybenzoate) / propyl (4-hydroxybenzoate) = E 218 / E 216, sodium acetate, acetic acid, purified water.

What Zyrtec looks like and contents of the pack
Zyrtec is supplied as a clear and colorless liquid.

Pack with a bottle of 10, 15, 20, or 30 ml solution.

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]
{Name and address}
{tel}
{fax}
{e-mail}

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria: Zyrtec 10 mg/ml -Tropfen
Belgium: Cetirizine-UCB, Zyrtec, Virlix
Bulgaria: Zyrtec
Czech Republic: Zyrtec
Denmark: Zyrtec
Estonia: Zyrtec
Finland: Zyrtec
France: Virlix, Zyrtec
Germany: Zyrtec P tropfen, Zyrtec tropfen
Greece: Ziptek
Hungary: Zyrtec cseppek
Italy: Formistin, Virlix, Zirtec 10mg/ml gocce orali soluzione
Latvia: Zyrtec
Lithuania: Zyrtec
Luxembourg: Virlix, Zyrtec, Cetirizine-UCB
Norway: Zyrtec
Poland: Zyrtec
Portugal: Zyrtec
Romania: Zyrtec
Slovak Republic: Zyrtec gtt por 10mg/ml
Slovenia: Zyrtec10 mg/ml peroralne kapljice, raztopina
Spain: Alerlisin, Virdos, Zyrtec gotas orales en solución
Sweden: Zyrlex

This leaflet was last approved in {MM/YYYY}.

[To be completed nationally]

PACKAGE LEAFLET
For medicinal products available without a prescription

PACKAGE LEAFLET: INFORMATION FOR THE USER

Zyrtec and associated names (see Annex I) 10 mg/ml oral drops, solution

Cetirizine dihydrochloride

Read all of this leaflet carefully because it contains important information for you.
This medicine is available without prescription. However, you still need to use Zyrtec carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 3 days.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT Zyrtec IS AND WHAT IT IS USED FOR

Cetirizine dihydrochloride is the active ingredient of Zyrtec. Zyrtec is an antiallergic medication.

In adults and paediatric patients aged 1 year and above, Zyrtec is indicated
- for the relief of nasal and ocular symptoms of seasonal and perennial allergic rhinitis.
- for the relief of chronic nettle rash (chronic idiopathic urticaria).

2. BEFORE YOU TAKE ZYRTEC

Do not take Zyrtec
- if you have a severe kidney disease (severe renal failure with creatinine clearance below 10 ml/min);
- if you are known to be hypersensitive to the active substance of Zyrtec, to any of its excipients (other constituents), to hydroxyzine or to any piperazine derivatives (closely related active substances of other medicines).

Take special care with Zyrtec
If you are a patient with renal insufficiency. Please ask your doctor for advice; if necessary, you will take a lower dose. The new dose will be determined by your Doctor.

If you are an epileptic patient or a patient at risk of convulsions, you should ask your doctor for advice.

No interactions suceptible to have a noticeable impact have been observed between alcohol (at the blood level of 0.5 per mille corresponding to one glass of wine) and cetirizine used at the normal doses. However, as it is the case with all antihistamines, it is recommended to avoid concurrent consumption of alcohol.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken other medicine, including medicines obtained without a prescription.

Due to the profile of cetirizine, no interactions with other drugs are expected.

Taking Zyrtec with food and drink
Food does not affect noticeabily the absorption of cetirizine.

Pregnancy and breast-feeding
Ask your doctor for advice before taking any medicine.

As with other drugs, use of Zyrtec should be avoided in pregnant women. Accidental use of the drug by a pregnant women should not produce any harmful effects on the foetus. Nevertheless, the administration of the medicine should be discontinued.

You should not take Zyrtec during breast feeding because cetirizine passes into breast milk.

Driving and using machines
Clinical studies have produced no evidence of impaired attention, alertness and driving capabilities after taking Zyrtec at the recommended dose.
If you are intending to drive, engage in potentially hazardous activities or operate machinery, you should not exceed the recommended dose. You should closely observe your response to the drug.
If you are a sensitive patient, you may find that the simultaneous use of alcohol or other nervous depressant agents may additionally affect your attention and ability to react.

Important information about some of the ingredients of Zyrtec
Zyrtec oral drops solution contain methyl (4-hydroxybenzoate) E 218 propyl (4-hydroxybenzoate) E 216 that may cause allergic reactions (possibly delayed).

3. HOW TO TAKE ZYRTEC

How and when should you take Zyrtec?
These guidelines apply unless your Doctor has given you different instructions on how to use Zyrtec. Please follow these instructions, otherwise Zyrtec may not be fully effective.

Adults and adolescents above 12 years old:
10 mg once daily as 20 drops

Children between 6 and 12 years old:
5 mg twice daily as 10 drops twice daily.

Children between 2 and 6 years old
2.5 mg twice daily administered as 5 drops twice daily

Patients with moderate to severe renal impairment
Patients with moderate renal impairment are recommended to take 5 mg as 10 drops once daily.

If you feel that the effect of Zyrtec is too weak or too strong, please consult your doctor.

Duration of treatment
The duration of treatment depends on the type, duration and course of your complaints and is determined by your doctor.

If you take more Zyrtec than you should
If you think you have taken an overdose of Zyrtec please inform your doctor.
Your doctor will then decide what measures, if any, should be taken.

After an overdose, the side effects described below may occur with increased intensity. Adverse effects such as confusion, diarrhoea, dizziness, tiredness, headache, ailing, dilating of pupil, itching, restlessness, sedation, somnolence, stupor, abnormal rapid heart rate, tremors and urinary retention have been reported.

If you forget to take Zyrtec
Do not take a double dose to make up for forgotten dose

If you stop taking Zyrtec
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Zyrtec can cause side effects, although not everybody gets them.

Following side effects have been reported in post marketing experience. The frequencies are defined as such: (common: 1 patient out of 100 to 1 out of 10, uncommon: 1 out of 1,000 to 1 out of 100, rare: 1 out of 10,000 to 1 out of 1,000, very rare: less than 1 out of 10,000).

- Blood and lymphatic disorders:
  very rare: thrombocytopenia (low levels of blood platelets)

- Body as a whole:
  common: fatigue

- Cardiac disorders:
  rare: tachycardia (heart beating too fast)

- Eye disorders:
  very rare: accommodation disorder, blurred vision, oculogyration (eyes having uncontrolled circular movements)

- Gastro-intestinal disorders:
  common: dry mouth, nausea, diarrhoea
  uncommon:, abdominal pain,

- General disorders and administration site conditions:
  uncommon: asthenia (extreme fatigue), malaise,
  rare: oedema (swelling)

- Immune system disorders:
  rare: allergic reactions, some severe (very rare)

- Hepatobiliary disorders:
  rare: liver function abnormal

- Investigations:
  rare: weight increased

- Nervous system disorders:
  common: dizziness, headache

uncommon: paresthesia (abnormal feelings of the skin),
rare: convulsions, movements disorders
very rare: syncope, tremor, dysgeusia (altered taste)

- Psychiatric disorders:
  common: somnolence
  uncommon: agitation
  rare: aggression, confusion, depression, hallucination, insomnia
  very rare: tic

- Renal and urinary disorders:
  very rare: abnormal elimination of urine

- Respiratory system disorders:
  common: pharyngitis, rhinitis

- Skin and subcutaneous tissue disorders:
  uncommon: pruritus, rash,
  rare: urticaria,
  very rare: oedema, fixed drug eruption

If you develop one of the side effects described above, please inform your doctor. At the first signs of a hypersensitivity reaction, stop taking Zyrtec. **Your doctor will then assess the severity and decide on any further measures that may be necessary.**
If you think you have any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE ZYRTEC

Keep out of the reach and sight of children.

Do not use Zyrtec after the expiry date which is stated on the box and bottle.

This medicine does not require any special storage conditions.

6. FURTHER INFORMATION

What Zyrtec contains
- The active substance of Zyrtec is cetirizine dihydrochloride. One ml (equals to 20 drops) contains 10 mg of cetirizine dihydrochloride. One drop contains 0.5 mg of cetirizine dihydrochloride.
- The other ingredients are glycerol, propylène glycol, saccharine sodium, methyl (4-hydroxybenzoate) / propyl (4-hydroxybenzoate) = E 218 / E 216, sodium acetate, acetic acid, purified water.

What Zyrtec looks like and contents of the pack
Zyrtec is supplied as a clear and colorless liquid.

Pack with a bottle of 10, 15, 20, or 30 ml solution.

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]
{Name and address}
{tel}
{fax}
{e-mail}

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria: Zyrtec 10 mg/ml -Tropfen
Belgium: Cetirizine-UCB, Zyrtec, Virlix
Bulgaria: Zyrtec
Czech Republic: Zyrtec
Denmark: Zyrtec
Estonia: Zyrtec
Finland: Zyrtec
France: Virlix, Zyrtec
Germany: Zyrtec P tropfen, Zyrtec tropfen
Greece: Ziptek
Hungary: Zyrtec cseppek
Italy: Formistin, Virlix, Zirtec 10mg/ml gocce orali soluzione
Latvia: Zyrtec
Lithuania: Zyrtec
Luxembourg: Virlix, Zyrtec, Cetirizine-UCB
Norway: Zyrtec
Poland: Zyrtec
Portugal: Zyrtec
Romania: Zyrtec
Slovak Republic: Zyrtec gtt por 10mg/ml
Slovenia: Zyrtec10 mg/ml peroralne kapljice, raztopina
Spain: Alerlisin, Virdos, Zyrtec gotas orales en solución
Sweden: Zyrlex

This leaflet was last approved in {MM/YYYY}.

[To be completed nationally]

PACKAGE LEAFLET
For medicinal products available on prescription

PACKAGE LEAFLET: INFORMATION FOR THE USER

Zyrtec and associated names (see Annex I) 1 mg/ml oral solution

Cetirizine dihydrochloride

Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT Zyrtec IS AND WHAT IT IS USED FOR

Cetirizine dihydrochloride is the active ingredient of Zyrtec. Zyrtec is an antiallergic medication.

In adults and children aged 2 year and above, Zyrtec is indicated
- for the relief of nasal and ocular symptoms of seasonal and perennial allergic rhinitis.
- for the relief of chronic nettle rash (chronic idiopathic urticaria).

2. BEFORE YOU TAKE ZYRTEC

Do not take Zyrtec
- if you have a severe kidney disease (severe renal failure with creatinine clearance below 10 ml/min);
- if you are known to be hypersensitive to the active substance of Zyrtec, to any of its excipients (other constituents), to hydroxyzine or to any piperazine derivatives (closely related active substances of other medicines).

You should not take Zyrtec 1 mg/ml oral solution*:*
- if you have rare hereditary problems of fructose intolerance

Take special care with Zyrtec
If you are a patient with renal insufficiency, please ask your doctor for advice; if necessary, you will take a lower dose. The new dose will be determined by your doctor.

If you are an epileptic patient or a patient at risk of convulsions, you should ask your doctor for advice.

No interactions suceptible to have a noticeable impact have been observed between alcohol (at the blood level of 0.5 per mille corresponding to one glass of wine) and cetirizine used at the normal doses. However, as it is the case with all antihistamines, it is recommended to avoid concurrent consumption of alcohol.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Due to the profile of cetirizine, no interactions with other drugs are expected.

Taking Zyrtec with food and drink
Food does not affect noticeabily the absorption of cetirizine.

Pregnancy and breast-feeding
Ask your doctor for advice before taking any medicine.

As with other drugs, use of Zyrtec should be avoided in pregnant women. Accidental use of the drug by a pregnant woman should not produce any harmful effects on the foetus. Nevertheless, the administration of the medicine should be discontinued.

You should not take Zyrtec during breast feeding because cetirizine passes into breast milk.

Driving and using machines
Clinical studies have produced no evidence of impaired attention, alertness and driving capabilities after taking Zyrtec at the recommended dose.
If you are intending to drive, engage in potentially hazardous activities or operate machinery, you should not exceed the recommended dose. You should closely observe your response to the drug.
If you are a sensitive patient, you may find that the simultaneous use of alcohol or other nervous depressant agents may additionally affect your attention and ability to react.

Important information about some of the ingredients of Zyrtec
Zyrtec oral solution contains sorbitol; if you have been told by your doctor that you have an intolerance to some sugars, please contact your doctor before taking this medicinal product.

Zyrtec oral solution contain methyl (4-hydroxybenzoate) E 218, propyl (4-hydroxybenzoate) E 216 that may cause allergic reactions (possibly delayed).

3. HOW TO TAKE ZYRTEC

How and when should you take Zyrtec?

These guidelines apply unless your doctor has given you different instructions on how to use Zyrtec. Please follow these instructions, otherwise Zyrtec may not be fully effective.

The solution can be swallowed as such.

Adults and adolescents above 12 years old:
10 mg once daily as 10 ml oral solution (2 full measuring spoons)

Children between 6 and 12 years old:
5 mg twice daily as 5 ml (one full measuring spoon) twice daily.

Children between 2 and 6 years old
2.5 mg twice daily as 2.5 ml oral solution (a half-measuring spoon) twice daily

Patients with moderate to severe renal impairment
Patients with moderate renal impairment are recommended to take 5 mg once daily.

If you feel that the effect of Zyrtec is too weak or too strong, please consult your doctor.

Duration of treatment:
The duration of treatment depends on the type, duration and course of your complaints and is determined by your doctor.

If you take more Zyrtec than you should
If you think you have taken an overdose of Zyrtec please inform your doctor. Your doctor will then decide what measures, if any, should be taken.

After an overdose, the side effects described below may occur with increased intensity. Adverse effects such as confusion, diarrhoea, dizziness, tiredness, headache, ailing, dilating of pupil, itching, restlessness, sedation, somnolence, stupor, abnormal rapid heart rate, tremors and urinary retention have been reported.

If you forget to take Zyrtec
Do not take a double dose to make up for forgotten dose.

If you stop taking Zyrtec
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Zyrtec can cause side effects, although not everybody gets them.

Following side effects have been reported in post marketing experience. The frequencies are defined as such: (common: 1 patient out of 100 to 1 out of 10, uncommon: 1 out of 1,000 to 1 out of 100, rare: 1 out of 10,000 to 1 out of 1,000, very rare: less than 1 out of 10,000).

- Blood and lymphatic disorders:
  very rare: thrombocytopenia (low levels of blood platelets)

- Body as a whole:
  common: fatigue

- Cardiac disorders:
  rare: tachycardia (heart beating too fast)

- Eye disorders:
  very rare: accommodation disorder, blurred vision, oculogyration (eyes having uncontrolled circular movements)

- Gastro-intestinal disorders:
  common: dry mouth, nausea, diarrhoea
  uncommon:, abdominal pain,

- General disorders and administration site conditions:
  uncommon: asthenia (extreme fatigue), malaise,
  rare: oedema (swelling)

- Immune system disorders:
  rare: allergic reactions, some severe (very rare)

- Hepatobiliary disorders:
  rare: liver function abnormal

- Investigations:
  rare: weight increased

- Nervous system disorders:
  common: dizziness, headache
  uncommon: paresthesia (abnormal feelings of the skin),
  rare: convulsions, movements disorders
  very rare: syncope, tremor, dysgeusia (altered taste)

- Psychiatric disorders:
  common: somnolence
  uncommon: agitation
  rare: aggression, confusion, depression, hallucination, insomnia
  very rare: tic

- Renal and urinary disorders:
  very rare: abnormal elimination of urine

- Respiratory system disorders:
  common: pharyngitis, rhinitis

- Skin and subcutaneous tissue disorders:
  uncommon: pruritus, rash,
  rare: urticaria,
  very rare: oedema, fixed drug eruption

If you develop one of the side effects described above, please inform your doctor. At the first signs of hypersensitivity reaction, stop taking Zyrtec. Your doctor will then assess the severity and decide on any further measures that may be necessary.
If you think you have any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE ZYRTEC

Keep out of the reach and sight of children.

Do not use Zyrtec after the expiry date which is stated on the box and bottle.

This medicine does not require any special storage conditions.

6. FURTHER INFORMATION

What Zyrtec contains

- The active substance of Zyrtec Oral solution is cetirizine. 10 ml (equals to 2 measuring spoons) contain 10 mg of cetirizine dihydrochloride.
- The other ingredients are sorbitol (E 420), glycerol, propylene glycol, saccharine sodium, methyl (4-hydroxybenzoate) / propyl (4-hydroxybenzoate) = E 218 / E 216, flavouring agent, sodium acetate, acetic acid, purified water.
- 10 ml Zyrtec oral solution (=2 measuring spoons) contain: 3.15 g glucose equivalents (sorbitol).

What Zyrtec looks like and contents of the pack

Clear and colorless liquid with slightly sweet taste and a banana flavor

Pack with a bottle of 60, 75, 100, 125, 150, or 200 mL solution.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]
{Name and address}
{tel}
{fax}
{e-mail}

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria: Zyrtec 1 mg/ml – orale Lösung
Belgium: Zyrtec
Cyprus: Zyrtec
Denmark: Benaday, Zyrtec
Estonia: Zyrtec
Finland: Zyrtec
France: Virlix, Zyrtec
Germany: Zyrtec saft
Hungary: Zyrtec oldat
Ireland: Zirtek oral solution 1mg/ml
Italy: Zirtec 1mg/ml soluzione orale
Latvia: Zyrtec
Lithuania: Zyrtec
Luxembourg: Zyrtec
Malta: Zyrtec
Netherlands: Zyrtec
Norway: Zyrtec
Poland: Virlix, Zyrtec
Portugal: Zyrtec, Virlix
Slovenia: Zyrtec1 mg/ml peroralna raztopina
Spain: Alerlisin, Virlix, Reactine 5mg/5ml solución oral, Zyrtec solución oral
Sweden: Zyrlex
United Kingdom: Benadryl allergy oral syrup, Benadryl for children allergy solution, Zirtek allergy relief for children, Zirtek allergy solution, Benadryl allergy solution, Benadryl allergy oral solution

This leaflet was last approved in {MM/YYYY}.

[To be completed nationally]

PACKAGE LEAFLET
For medicinal products available without a prescription

PACKAGE LEAFLET: INFORMATION FOR THE USER

Zyrtec and associated names (see Annex I) 1 mg/ml oral solution

Cetirizine dihydrochloride

Read all of this leaflet carefully because it contains important information for you.
This medicine is available without prescription. However, you still need to use Zyrtec carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 3 days.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT Zyrtec IS AND WHAT IT IS USED FOR

Cetirizine dihydrochloride is the active ingredient of Zyrtec. Zyrtec is an antiallergic medication.

In adults and children aged 2 year and above, Zyrtec is indicated
- for the relief of nasal and ocular symptoms of seasonal and perennial allergic rhinitis.
- for the relief of chronic nettle rash (chronic idiopathic urticaria).

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Taking Zyrtec with food and drink
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Pregnancy and breast-feeding
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If you are intending to drive, engage in potentially hazardous activities or operate machinery, you should not exceed the recommended dose. You should closely observe your response to the drug.
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Important information about some of the ingredients of Zyrtec
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Zyrtec oral solution contain methyl (4-hydroxybenzoate) E 218, propyl (4-hydroxybenzoate) E 216 that may cause allergic reactions (possibly delayed).

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- Immune system disorders:
  rare: allergic reactions, some severe (very rare)

- Hepatobiliary disorders:
  rare: liver function abnormal

- Investigations:
  rare: weight increased

- Nervous system disorders:
  common: dizziness, headache
  uncommon: paresthesia (abnormal feelings of the skin),
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- Psychiatric disorders:
  common: somnolence
  uncommon: agitation
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  very rare: abnormal elimination of urine

- Respiratory system disorders:
  common: pharyngitis, rhinitis

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If you think you have any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE ZYRTEC

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This medicine does not require any special storage conditions.

6. FURTHER INFORMATION

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Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]
{Name and address}
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Estonia: Zyrtec
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France: Virlix, Zyrtec
Germany: Zyrtec saft
Hungary: Zyrtec oldat
Ireland: Zirtek oral solution 1mg/ml
Italy: Zirtec 1mg/ml soluzione orale
Latvia: Zyrtec
Lithuania: Zyrtec
Luxembourg: Zyrtec
Malta: Zyrtec
Netherlands: Zyrtec
Norway: Zyrtec
Poland: Virlix, Zyrtec
Portugal: Zyrtec, Virlix
Slovenia: Zyrtec1 mg/ml peroralna raztopina
Spain: Alerlisin, Virlix, Reactine 5mg/5ml solución oral, Zyrtec solución oral
Sweden: Zyrlex
United Kingdom: Benadryl allergy oral syrup, Benadryl for children allergy solution, Zirtek allergy relief for children, Zirtek allergy solution, Benadryl allergy solution, Benadryl allergy oral solution

This leaflet was last approved in {MM/YYYY}.

[To be completed nationally]