ANNEX I

LIST OF THE NAMES, PHARMACEUTICAL FORM(S), STRENGTH(S) OF THE MEDICINAL PRODUCT(S), ROUTE(S) OF ADMINISTRATION, APPLICANT(S) / MARKETING AUTHORISATION HOLDER(S) IN THE MEMBER STATES

Member State EU/EEA	**Marketing Authorisation Holder**	**Invented name Name**	**Strength**	**Pharmaceutical Form**	**Route of administration**
Austria	Pfizer Corporation Austria Ges.m.b.H. Floridsdorfer Hauptstraße 1 A - 1210 Wien Austria	Sortis 10 mg - Filmtabletten	10mg	Film-coated tablet	Oral use
Austria	Pfizer Corporation Austria Ges.m.b.H. Floridsdorfer Hauptstraße 1 A - 1210 Wien Austria	Sortis 20 mg - Filmtabletten	20mg	Film-coated tablet	Oral use
Austria	Pfizer Corporation Austria Ges.m.b.H. Floridsdorfer Hauptstraße 1 A - 1210 Wien Austria	Sortis 40 mg - Filmtabletten	40mg	Film-coated tablet	Oral use
Austria	Pfizer Corporation Austria Ges.m.b.H. Floridsdorfer Hauptstraße 1 A - 1210 Wien Austria	Sortis 80 mg - Filmtabletten	80mg	Film-coated tablet	Oral use
Belgium	Pfizer SA Boulevard de la Plaine 17 B-1050 Brussels, Belgium	Lipitor	10mg	Film-coated tablet	Oral use
Belgium	Pfizer SA Boulevard de la Plaine 17 B-1050 Brussels, Belgium	Lipitor	20mg	Film-coated tablet	Oral use

Member State EU/EEA	**Marketing Authorisation Holder**	**Invented name Name**	**Strength**	**Pharmaceutical Form**	**Route of administration**
Belgium	Pfizer SA Boulevard de la Plaine 17 B-1050 Brussels, Belgium	Lipitor	40mg	Film-coated tablet	Oral use
Belgium	Pfizer SA Boulevard de la Plaine 17 B-1050 Brussels, Belgium	Lipitor	80mg	Film-coated tablet	Oral use
Bulgaria	Pfizer Europe MA EEIG, Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom	Sortis	10mg	Film-coated tablet	Oral use
Bulgaria	Pfizer Europe MA EEIG, Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom	Sortis	20mg	Film-coated tablet	Oral use
Bulgaria	Pfizer Europe MA EEIG, Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom	Sortis	40mg	Film-coated tablet	Oral use

Member State EU/EEA	**Marketing Authorisation Holder**	**Invented name Name**	**Strength**	**Pharmaceutical Form**	**Route of administration**
Bulgaria	Pfizer Europe MA EEIG, Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom	Sortis	80mg	Film-coated tablet	Oral use
Cyprus	Pfizer Hellas A. E. 243, Messoghion Ave., 154 51 Neo Psychiko, Athens, Greece	Lipitor	10mg	Film-coated tablet	Oral use
Cyprus	Pfizer Hellas A. E. 243, Messoghion Ave., 154 51 Neo Psychiko, Athens, Greece	Lipitor	20mg	Film-coated tablet	Oral use
Cyprus	Pfizer Hellas A. E. 243, Messoghion Ave., 154 51 Neo Psychiko, Athens, Greece	Lipitor	40mg	Film-coated tablet	Oral use
Czech Republic	Pfizer, spol. s r.o., Stroupežnického 17, 150 00 Prague 5, Czech Republic	Sortis	10mg	Film-coated tablet	Oral use
Czech Republic	Pfizer, spol. s r.o., Stroupežnického 17, 150 00 Prague 5, Czech Republic	Sortis	20mg	Film-coated tablet	Oral use

Member State EU/EEA	**Marketing Authorisation Holder**	**Invented name Name**	**Strength**	**Pharmaceutical Form**	**Route of administration**
Czech Republic	Pfizer, spol. s r.o., Stroupežnického 17, 150 00 Prague 5, Czech Republic	Sortis	40mg	Film-coated tablet	Oral use
Czech Republic	Pfizer, spol. s r.o., Stroupežnického 17, 150 00 Prague 5, Czech Republic	Sortis	80mg	Film-coated tablet	Oral use
Denmark	Pfizer ApS, Lautrupvang 8, 2750 Ballerup, Denmark	Zarator	10mg	Film-coated tablet	Oral use
Denmark	Pfizer ApS, Lautrupvang 8, 2750 Ballerup, Denmark	Zarator	20mg	Film-coated tablet	Oral use
Denmark	Pfizer ApS, Lautrupvang 8, 2750 Ballerup, Denmark	Zarator	40mg	Film-coated tablet	Oral use
Denmark	Pfizer ApS, Lautrupvang 8, 2750 Ballerup, Denmark	Zarator	80mg	Film-coated tablet	Oral use
Estonia	Pfizer Europe MA EEIG, Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom	Sortis	10mg	Film-coated tablet	Oral use

Member State EU/EEA	**Marketing Authorisation Holder**	**Invented name Name**	**Strength**	**Pharmaceutical Form**	**Route of administration**
Estonia	Pfizer Europe MA EEIG, Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom	Sortis	20mg	Film-coated tablet	Oral use
Estonia	Pfizer Europe MA EEIG, Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom	Sortis	40mg	Film-coated tablet	Oral use
Estonia	Pfizer Europe MA EEIG, Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom	Sortis 80 mg	80mg	Film-coated tablet	Oral use
Finland	Pfizer Oy, Tietokuja 4, 00330 Helsinki, Finland	Lipitor	10mg	Film-coated tablet	Oral use
Finland	Pfizer Oy, Tietokuja 4, 00330 Helsinki, Finland	Lipitor	20mg	Film-coated tablet	Oral use
Finland	Pfizer Oy, Tietokuja 4, 00330 Helsinki, Finland	Lipitor	40mg	Film-coated tablet	Oral use
Finland	Pfizer Oy, Tietokuja 4, 00330 Helsinki, Finland	Lipitor	80mg	Film-coated tablet	Oral use

Member State EU/EEA	**Marketing Authorisation Holder**	**Invented name Name**	**Strength**	**Pharmaceutical Form**	**Route of administration**
Finland	Pfizer Oy, Tietokuja 4, 00330 Helsinki, Finland	Orbeos	10mg	Film-coated tablet	Oral use
Finland	Pfizer Oy, Tietokuja 4, 00330 Helsinki, Finland	Orbeos	20mg	Film-coated tablet	Oral use
Finland	Pfizer Oy, Tietokuja 4, 00330 Helsinki, Finland	Orbeos	40mg	Film-coated tablet	Oral use
Finland	Pfizer Oy, Tietokuja 4, 00330 Helsinki, Finland	Orbeos	80mg	Film-coated tablet	Oral use
France	Pfizer Holding France 23-25 Avenue du Docteur Lannelongue 75668 Paris Cedex 14 France	Tahor	10mg	Film-coated tablet	Oral use
France	Pfizer Holding France 23-25 Avenue du Docteur Lannelongue 75668 Paris Cedex 14 France	Tahor	20mg	Film-coated tablet	Oral use
France	Pfizer Holding France 23-25 Avenue du Docteur Lannelongue 75668 Paris Cedex 14 France	Tahor	40mg	Film-coated tablet	Oral use

Member State EU/EEA	**Marketing Authorisation Holder**	**Invented name Name**	**Strength**	**Pharmaceutical Form**	**Route of administration**
France	Pfizer Holding France 23-25 Avenue du Docteur Lannelongue 75668 Paris Cedex 14 France	Tahor	80mg	Film-coated tablet	Oral use
Germany	Pfizer Pharma GmbH, Linkstraße 10 10785 Berlin, Germany	Sortis 10 mg	10mg	Film-coated tablet	Oral use
Germany	Pfizer Pharma GmbH, Linkstraße 10 10785 Berlin, Germany	Sortis 20 mg	20mg	Film-coated tablet	Oral use
Germany	Pfizer Pharma GmbH, Linkstraße 10 10785 Berlin, Germany	Sortis 40 mg	40mg	Film-coated tablet	Oral use
Germany	Pfizer Pharma GmbH, Linkstraße 10 10785 Berlin, Germany	Sortis 80 mg	80mg	Film-coated tablet	Oral use
Germany	Pfizer Pharma GmbH, Linkstraße 10 10785 Berlin, Germany	Liprimar 10 mg	10mg	Film-coated tablet	Oral use
Germany	Pfizer Pharma GmbH, Linkstraße 10 10785 Berlin, Germany	Liprimar 20 mg	20mg	Film-coated tablet	Oral use
Germany	Pfizer Pharma GmbH, Linkstraße 10 10785 Berlin, Germany	Liprimar 40 mg	40mg	Film-coated tablet	Oral use
Germany	Pfizer Pharma GmbH, Linkstraße 10 10785 Berlin, Germany	Liprimar 80 mg	80mg	Film-coated tablet	Oral use

Member State EU/EEA	**Marketing Authorisation Holder**	**Invented name Name**	**Strength**	**Pharmaceutical Form**	**Route of administration**
Germany	Pfizer Pharma GmbH, Linkstraße 10 10785 Berlin, Germany	Atorvastatin 10 mg PD	10mg	Film-coated tablet	Oral use
Germany	Pfizer Pharma GmbH, Linkstraße 10 10785 Berlin, Germany	Atorvastatin 20 mg PD	20mg	Film-coated tablet	Oral use
Germany	Pfizer Pharma GmbH, Linkstraße 10 10785 Berlin, Germany	Atorvastatin 40 mg PD	40mg	Film-coated tablet	Oral use
Germany	Pfizer Pharma GmbH, Linkstraße 10 10785 Berlin, Germany	Atorvastatin 80 mg PD	80mg	Film-coated tablet	Oral use
Greece	Pfizer Hellas A. E. 243, Messoghion Ave., 154 51 Neo Psychiko, Athens, Greece	Lipitor	10mg	Film-coated tablet	Oral use
Greece	Pfizer Hellas A. E. 243, Messoghion Ave., 154 51 Neo Psychiko, Athens, Greece	Lipitor	20mg	Film-coated tablet	Oral use
Greece	Pfizer Hellas A. E. 243, Messoghion Ave., 154 51 Neo Psychiko, Athens, Greece	Lipitor	40mg	Film-coated tablet	Oral use
Greece	Pfizer Hellas A. E. 243, Messoghion Ave., 154 51 Neo Psychiko, Athens, Greece	Lipitor	80mg	Film-coated tablet	Oral use

Member State EU/EEA	**Marketing Authorisation Holder**	**Invented name Name**	**Strength**	**Pharmaceutical Form**	**Route of administration**
Greece	WIN MEDICA Ltd 41 Papadiamantopoulou Street 115 28 Ilisia Athens, Greece	Zarator	10mg	Film-coated tablet	Oral use
Greece	WIN MEDICA Ltd 41 Papadiamantopoulou Street 115 28 Ilisia Athens, Greece	Zarator	20mg	Film-coated tablet	Oral use
Greece	WIN MEDICA Ltd 41 Papadiamantopoulou Street 115 28 Ilisia Athens, Greece	Zarator	40mg	Film-coated tablet	Oral use
Greece	Pfizer Hellas A. E. 243, Messoghion Ave., 154 51 Neo Psychiko, Athens, Greece	Edovin	10mg	Film-coated tablet	Oral use
Greece	Pfizer Hellas A. E. 243, Messoghion Ave., 154 51 Neo Psychiko, Athens, Greece	Edovin	20mg	Film-coated tablet	Oral use
Greece	Pfizer Hellas A. E. 243, Messoghion Ave., 154 51 Neo Psychiko, Athens, Greece	Edovin	40mg	Film-coated tablet	Oral use

Member State EU/EEA	**Marketing Authorisation Holder**	**Invented name Name**	**Strength**	**Pharmaceutical Form**	**Route of administration**
Hungary	Pfizer KFT, 1123 Budapest, Alkotás u. 53. MOM Park "F" Ép., Hungary	Sortis	10mg	Film-coated tablet	Oral use
Hungary	Pfizer KFT, 1123 Budapest, Alkotás u. 53. MOM Park "F" Ép., Hungary	Sortis	20mg	Film-coated tablet	Oral use
Hungary	Pfizer KFT, 1123 Budapest, Alkotás u. 53. MOM Park "F" Ép., Hungary	Sortis	40mg	Film-coated tablet	Oral use
Hungary	Pfizer KFT, 1123 Budapest, Alkotás u. 53. MOM Park "F" Ép., Hungary	Sortis	80mg	Film-coated tablet	Oral use
Hungary	C.P. Pharma Gyógyszerkereskedelmi Kft. 2040 Budaörs Vasút u. 11. Hungary	Obradon	10mg	Film-coated tablet	Oral use
Hungary	C.P. Pharma Gyógyszerkereskedelmi Kft. 2040 Budaörs Vasút u. 11. Hungary	Obradon	20mg	Film-coated tablet	Oral use

Member State EU/EEA	**Marketing Authorisation Holder**	**Invented name Name**	**Strength**	**Pharmaceutical Form**	**Route of administration**
Hungary	C.P. Pharma Gyógyszerkereskedelmi Kft. 2040 Budaörs Vasút u. 11. Hungary	Obradon	40mg	Film-coated tablet	Oral use
Hungary	C.P. Pharma Gyógyszerkereskedelmi Kft. 2040 Budaörs Vasút u. 11. Hungary	Obradon	80mg	Film-coated tablet	Oral use
Iceland	Pfizer ApS, Lautrupvang 8, 2750 Ballerup, Denmark	Zarator	10mg	Film-coated tablet	Oral use
Iceland	Pfizer ApS, Lautrupvang 8, 2750 Ballerup, Denmark	Zarator	20mg	Film-coated tablet	Oral use
Iceland	Pfizer ApS, Lautrupvang 8, 2750 Ballerup, Denmark	Zarator	40mg	Film-coated tablet	Oral use
Iceland	Pfizer ApS, Lautrupvang 8, 2750 Ballerup, Denmark	Zarator	80mg	Film-coated tablet	Oral use
Ireland	Pfizer Ireland Pharmaceuticals, Pottery Road, Dun Laoghaire, Co Dublin Ireland	Lipitor	10mg	Film-coated tablet	Oral use

Member State EU/EEA	**Marketing Authorisation Holder**	**Invented name Name**	**Strength**	**Pharmaceutical Form**	**Route of administration**
Ireland	Pfizer Ireland Pharmaceuticals, Pottery Road, Dun Laoghaire, Co Dublin Ireland	Lipitor	20mg	Film-coated tablet	Oral use
Ireland	Pfizer Ireland Pharmaceuticals, Pottery Road, Dun Laoghaire, Co Dublin Ireland	Lipitor	40mg	Film-coated tablet	Oral use
Ireland	Pfizer Ireland Pharmaceuticals, Pottery Road, Dun Laoghaire, Co Dublin Ireland	Lipitor	80mg	Film-coated tablet	Oral use
Italy	Pfizer Italia S.r.l. Via Isonzo, 71 04100 Latina - Italy	Xarator	10mg	Film-coated tablet	Oral use
Italy	Pfizer Italia S.r.l. Via Isonzo, 71 04100 Latina - Italy	Xarator	20mg	Film-coated tablet	Oral use
Italy	Pfizer Italia S.r.l. Via Isonzo, 71 04100 Latina - Italy	Xarator	40mg	Film-coated tablet	Oral use
Italy	Pfizer Italia S.r.l. Via Isonzo, 71 04100 Latina - Italy	Xarator	80mg	Film-coated tablet	Oral use
Italy	Bioindustria Farmaceutici S.r.l Via Isonzo, 71 04100 Latina - Italy	Lipitor	10mg	Film-coated tablet	Oral use

Member State EU/EEA	**Marketing Authorisation Holder**	**Invented name Name**	**Strength**	**Pharmaceutical Form**	**Route of administration**
Italy	Bioindustria Farmaceutici S.r.l. Via Isonzo, 71 04100 Latina - Italy	Lipitor	20mg	Film-coated tablet	Oral use
Italy	Bioindustria Farmaceutici S.r.l. Via Isonzo, 71 04100 Latina - Italy	Lipitor	40mg	Film-coated tablet	Oral use
Italy	Bioindustria Farmaceutici S.r.l. Via Isonzo, 71 04100 Latina - Italy	Lipitor	80mg	Film-coated tablet	Oral use
Italy	Pfizer Italia S.r.l. Via Isonzo, 71 04100 Latina - Italy	Torvast	10mg	Film-coated tablet	Oral use
Italy	Pfizer Italia S.r.l. Via Isonzo, 71 04100 Latina - Italy	Torvast	20mg	Film-coated tablet	Oral use
Italy	Pfizer Italia S.r.l. Via Isonzo, 71 04100 Latina - Italy	Torvast	40mg	Film-coated tablet	Oral use
Italy	Pfizer Italia S.r.l. Via Isonzo, 71 04100 Latina - Italy	Torvast	80mg	Film-coated tablet	Oral use
Italy	Laboratori Guidotti S.p.A. Via Livornese, 897 - La Vettola 56010 Pisa - Italy	Totalip	10mg	Film-coated tablet	Oral use

Member State EU/EEA	**Marketing Authorisation Holder**	**Invented name Name**	**Strength**	**Pharmaceutical Form**	**Route of administration**
Italy	Laboratori Guidotti S.p.A. Via Livornese, 897 - La Vettola 56010 Pisa - Italy	Totalip	20mg	Film-coated tablet	Oral use
Italy	Laboratori Guidotti S.p.A. Via Livornese, 897 - La Vettola 56010 Pisa - Italy	Totalip	40mg	Film-coated tablet	Oral use
Italy	Laboratori Guidotti S.p.A. Via Livornese, 897 - La Vettola 56010 Pisa - Italy	Totalip	80mg	Film-coated tablet	Oral use
Latvia	Pfizer Limited, Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	Sortis	10mg	Film-coated tablet	Oral use
Latvia	Pfizer Limited, Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	Sortis	20mg	Film-coated tablet	Oral use
Latvia	Pfizer Limited, Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	Sortis	40mg	Film-coated tablet	Oral use
Latvia	Pfizer Limited, Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	Sortis	80mg	Film-coated tablet	Oral use

Member State EU/EEA	**Marketing Authorisation Holder**	**Invented name Name**	**Strength**	**Pharmaceutical Form**	**Route of administration**
Lithuania	Pfizer Limited, Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom	Sortis	10mg	Film-coated tablet	Oral use
Lithuania	Pfizer Limited, Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom	Sortis	20mg	Film-coated tablet	Oral use
Lithuania	Pfizer Limited, Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom	Sortis	40mg	Film-coated tablet	Oral use
Lithuania	Pfizer Limited, Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom	Sortis	80mg	Film-coated tablet	Oral use
Luxembourg	Pfizer SA Boulevard de la Plaine 17 B-1050 Brussels, Belgium	Lipitor	10mg	Film-coated tablet	Oral use
Luxembourg	Pfizer SA Boulevard de la Plaine 17 B-1050 Brussels, Belgium	Lipitor	20mg	Film-coated tablet	Oral use
Luxembourg	Pfizer SA Boulevard de la Plaine 17 B-1050 Brussels, Belgium	Lipitor	40mg	Film-coated tablet	Oral use

Member State EU/EEA	**Marketing Authorisation Holder**	**Invented name Name**	**Strength**	**Pharmaceutical Form**	**Route of administration**
Luxembourg	Pfizer SA Boulevard de la Plaine 17 B-1050 Brussels, Belgium	Lipitor	80mg	Film-coated tablet	Oral use
Malta	Pfizer Hellas S.A. 243, Messoghion Ave., 154 51 Neo Psychiko, Athens, Greece	Lipitor	10mg	Film-coated tablet	Oral use
Malta	Pfizer Hellas S.A. 243, Messoghion Ave., 154 51 Neo Psychiko, Athens, Greece	Lipitor	20mg	Film-coated tablet	Oral use
Malta	Pfizer Hellas S.A. 243, Messoghion Ave., 154 51 Neo Psychiko, Athens, Greece	Lipitor	40mg	Film-coated tablet	Oral use
Malta	Pfizer Hellas S.A. 243, Messoghion Ave., 154 51 Neo Psychiko, Athens, Greece	Lipitor	80mg	Film-coated tablet	Oral use
Netherlands	Pfizer bv Rivium Westlaan 142 2909 LD Capelle a/d IJssel The Netherlands	Lipitor	10mg	Film-coated tablet	Oral use

Member State EU/EEA	**Marketing Authorisation Holder**	**Invented name Name**	**Strength**	**Pharmaceutical Form**	**Route of administration**
Netherlands	Pfizer bv Rivium Westlaan 142 2909 LD Capelle a/d IJssel The Netherlands	Lipitor	20mg	Film-coated tablet	Oral use
Netherlands	Pfizer bv Rivium Westlaan 142 2909 LD Capelle a/d IJssel The Netherlands	Lipitor	40mg	Film-coated tablet	Oral use
Netherlands	Pfizer bv Rivium Westlaan 142 2909 LD Capelle a/d IJssel The Netherlands	Lipitor	80mg	Film-coated tablet	Oral use
Norway	Pfizer AS Pb. 3 1324 Lysaker Norway	Lipitor	10mg	Film-coated tablet	Oral use
Norway	Pfizer AS Pb. 3 1324 Lysaker Norway	Lipitor	20mg	Film-coated tablet	Oral use
Norway	Pfizer AS Pb. 3 1324 Lysaker Norway	Lipitor	40mg	Film-coated tablet	Oral use
Norway	Pfizer AS Pb. 3 1324 Lysaker Norway	Lipitor	80mg	Film-coated tablet	Oral use

Member State EU/EEA	**Marketing Authorisation Holder**	**Invented name Name**	**Strength**	**Pharmaceutical Form**	**Route of administration**
Poland	Parke-Davis GmbH, Pfizerstrasse 1, 76 139 Karlsruhe, Germany	Sortis 10	10mg	Film-coated tablet	Oral use
Poland	Parke-Davis GmbH, Pfizerstrasse 1, 76 139 Karlsruhe, Germany	Sortis 20	20mg	Film-coated tablet	Oral use
Poland	Parke-Davis GmbH, Pfizerstrasse 1, 76 139 Karlsruhe, Germany	Sortis 40	40mg	Film-coated tablet	Oral use
Poland	Pfizer Polska Sp.z o.o. ul. Rzymowskiego 28 02-697 Warszawa Poland	Sortis 80	80 mg	Film-coated tablet	Oral use
Portugal	Laboratorios Pfizer, Lda., Lagoas Park, Edifício 10, 2740-271 Porto Salvo, Portugal	Zarator	10mg	Film-coated tablet	Oral use
Portugal	Laboratorios Pfizer, Lda., Lagoas Park, Edifício 10, 2740-271 Porto Salvo, Portugal	Zarator	20mg	Film-coated tablet	Oral use
Portugal	Laboratorios Pfizer, Lda., Lagoas Park, Edifício 10, 2740-271 Porto Salvo, Portugal	Zarator	40mg	Film-coated tablet	Oral use
Portugal	Laboratorios Pfizer, Lda., Lagoas Park, Edifício 10, 2740-271 Porto Salvo, Portugal	Zarator	80 mg	Film-coated tablet	Oral use

Member State EU/EEA	**Marketing Authorisation Holder**	**Invented name Name**	**Strength**	**Pharmaceutical Form**	**Route of administration**
Portugal	Parke-Davis - Produtos Farmaceuticos, Lda., Lagoas Park, Edifício 10, 2740-271 Porto Salvo, Portugal	Atorvastatina Parke-Davis	10mg	Film-coated tablet	Oral use
Portugal	Parke-Davis - Produtos Farmaceuticos, Lda., Lagoas Park, Edifício 10, 2740-271 Porto Salvo, Portugal	Atorvastatina Parke-Davis	20mg	Film-coated tablet	Oral use
Portugal	Parke-Davis - Produtos Farmaceuticos, Lda., Lagoas Park, Edifício 10, 2740-271 Porto Salvo, Portugal	Atorvastatina Parke-Davis	40mg	Film-coated tablet	Oral use
Portugal	Parke-Davis - Produtos Farmaceuticos, Lda., Lagoas Park, Edifício 10, 2740-271 Porto Salvo, Portugal	Atorvastatina Parke-Davis	80 mg	Film-coated tablet	Oral use
Portugal	Farmogene - Produtos Farmacêuticos, Lda, Lagoas Park, Edifício 10, 2740-271 Porto Salvo, Portugal	Texzor	10mg	Film-coated tablet	Oral use

Member State EU/EEA	**Marketing Authorisation Holder**	**Invented name Name**	**Strength**	**Pharmaceutical Form**	**Route of administration**
Portugal	Farmogene - Produtos Farmacêuticos, Lda, Lagoas Park, Edifício 10, 2740-271 Porto Salvo, Portugal	Texzor	20mg	Film-coated tablet	Oral use
Portugal	Farmogene - Produtos Farmacêuticos, Lda, Lagoas Park, Edifício 10, 2740-271 Porto Salvo, Portugal	Texzor	40mg	Film-coated tablet	Oral use
Portugal	Farmogene - Produtos Farmacêuticos, Lda., Lagoas Park, Edifício 10, 2740-271 Porto Salvo, Portugal	Texzor	80 mg	Film-coated tablet	Oral use
Romania	Pfizer Europe MA EEIG, Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom	Sortis	10mg	Film-coated tablet	Oral use
Romania	Pfizer Europe MA EEIG, Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom	Sortis	20mg	Film-coated tablet	Oral use
Romania	Pfizer Europe MA EEIG, Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom	Sortis	40mg	Film-coated tablet	Oral use

Member State EU/EEA	**Marketing Authorisation Holder**	**Invented name Name**	**Strength**	**Pharmaceutical Form**	**Route of administration**
Romania	Pfizer Europe MA EEIG, Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom	Sortis	80 mg	Film-coated tablet	Oral use
Slovak Republic	Pfizer Europe MA EEIG, Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom	Sortis	10mg	Film-coated tablet	Oral use
Slovak Republic	Pfizer Europe MA EEIG, Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom	Sortis	20mg	Film-coated tablet	Oral use
Slovak Republic	Pfizer Europe MA EEIG, Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom	Sortis	40mg	Film-coated tablet	Oral use
Slovak Republic	Pfizer Europe MA EEIG, Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom	Sortis	80 mg	Film-coated tablet	Oral use

Member State EU/EEA	**Marketing Authorisation Holder**	**Invented name Name**	**Strength**	**Pharmaceutical Form**	**Route of administration**
Slovenia	Pfizer Luxembourg SARL, 51, Avenue J. F. Kennedy, L-1855 Luxembourg, Luxembourg	Sortis 10 mg filmsko obložene tablete	10mg	Film-coated tablet	Oral use
Slovenia	Pfizer Luxembourg SARL, 51, Avenue J. F. Kennedy, L-1855 Luxembourg, Luxembourg	Sortis 20 mg filmsko obložene tablete	20mg	Film-coated tablet	Oral use
Slovenia	Pfizer Luxembourg SARL, 51, Avenue J. F. Kennedy, L-1855 Luxembourg, Luxembourg	Sortis 40 mg filmsko obložene tablete	40mg	Film-coated tablet	Oral use
Slovenia	Pfizer Luxembourg SARL, 51, Avenue J. F. Kennedy, L-1855 Luxembourg, Luxembourg	Sortis 80 mg filmsko obložene tablete	80 mg	Film-coated tablet	Oral use
Spain	Parke Davis. S.L. Avda. de Europa 20B Parque Empresarial la Moraleja 28108 Alcobendas, (Madrid) Spain	Zarator	10mg	Film-coated tablet	Oral use

Member State EU/EEA	**Marketing Authorisation Holder**	**Invented name Name**	**Strength**	**Pharmaceutical Form**	**Route of administration**
Spain	Parke Davis. S.L. Avda. de Europa 20B Parque Empresarial la Moraleja 28108 Alcobendas, (Madrid) Spain	Zarator	20mg	Film-coated tablet	Oral use
Spain	Parke Davis. S.L. Avda. de Europa 20B Parque Empresarial la Moraleja 28108 Alcobendas, (Madrid) Spain	Zarator	40mg	Film-coated tablet	Oral use
Spain	Parke Davis. S.L. Avda. de Europa 20B Parque Empresarial la Moraleja 28108 Alcobendas, (Madrid) Spain	Zarator	80 mg	Film-coated tablet	Oral use
Spain	Pfizer, S.A. Avda. de Europa 20B Parque Empresarial la Moraleja 28108 Alcobendas, (Madrid) Spain	Cardyl	10mg	Film-coated tablet	Oral use

Member State EU/EEA	**Marketing Authorisation Holder**	**Invented name Name**	**Strength**	**Pharmaceutical Form**	**Route of administration**
Spain	Pfizer, S.A. Avda. de Europa 20B Parque Empresarial la Moraleja 28108 Alcobendas, (Madrid) Spain	Cardyl	20mg	Film-coated tablet	Oral use
Spain	Pfizer, S.A. Avda. de Europa 20B Parque Empresarial la Moraleja 28108 Alcobendas, (Madrid) Spain	Cardyl	40mg	Film-coated tablet	Oral use
Spain	Pfizer, S.A. Avda. de Europa 20B Parque Empresarial la Moraleja 28108 Alcobendas, (Madrid) Spain	Cardyl	80 mg	Film-coated tablet	Oral use
Spain	Nostrum Farma, S.A., Avda. de Europa 20B Parque Empresarial la Moraleja 28108 Alcobendas, (Madrid) Spain	Atorvastatina Nostrum	10mg	Film-coated tablet	Oral use

Member State EU/EEA	**Marketing Authorisation Holder**	**Invented name Name**	**Strength**	**Pharmaceutical Form**	**Route of administration**
Spain	Nostrum Farma, S.A., Avda. de Europa 20B Parque Empresarial la Moraleja 28108 Alcobendas, (Madrid) Spain	Atorvastatina Nostrum	20mg	Film-coated tablet	Oral use
Spain	Nostrum Farma, S.A., Avda. de Europa 20B Parque Empresarial la Moraleja 28108 Alcobendas, (Madrid) Spain	Atorvastatina Nostrum	40mg	Film-coated tablet	Oral use
Spain	Nostrum Farma, S.A., Avda. de Europa 20B Parque Empresarial la Moraleja 28108 Alcobendas, (Madrid) Spain	Atorvastatina Nostrum	80 mg	Film-coated tablet	Oral use
Spain	PHARMACIA GRUPO PFIZER, S.L. Avda. de Europa 20B Parque Empresarial la Moraleja 28108 Alcobendas, (Madrid) Spain	Atorvastatina Pharmacia	10mg	Film-coated tablet	Oral use

Member State EU/EEA	**Marketing Authorisation Holder**	**Invented name Name**	**Strength**	**Pharmaceutical Form**	**Route of administration**
Spain	PHARMACIA GRUPO PFIZER, S.L. .Avda. de Europa 20B Parque Empresarial la Moraleja 28108 Alcobendas, (Madrid) Spain	Atorvastatina Pharmacia	20mg	Film-coated tablet	Oral use
Spain	PHARMACIA GRUPO PFIZER, S.L. Avda. de Europa 20B Parque Empresarial la Moraleja 28108 Alcobendas, (Madrid) Spain	Atorvastatina Pharmacia	40mg	Film-coated tablet	Oral use
Spain	PHARMACIA GRUPO PFIZER, S.L. Avda. de Europa 20B Parque Empresarial la Moraleja 28108 Alcobendas, (Madrid) Spain	Atorvastatina Pharmacia	80 mg	Film-coated tablet	Oral use
Spain	Almirall S.A. General Mitre, 151 08022 - Barcelona Spain	Prevencor	10mg	Film-coated tablet	Oral use

Member State EU/EEA	**Marketing Authorisation Holder**	**Invented name Name**	**Strength**	**Pharmaceutical Form**	**Route of administration**
Spain	Almirall S.A. General Mitre, 151 08022 - Barcelona Spain	Prevencor	20mg	Film-coated tablet	Oral use
Spain	Almirall S.A. General Mitre, 151 08022 - Barcelona Spain	Prevencor	40mg	Film-coated tablet	Oral use
Spain	Almirall S.A. General Mitre, 151 08022 - Barcelona Spain	Prevencor	80 mg	Film-coated tablet	Oral use
Sweden	Pfizer AB 191 90 Sollentuna Sweden	Lipitor	10mg	Film-coated tablet	Oral use
Sweden	Pfizer AB 191 90 Sollentuna Sweden	Lipitor	20mg	Film-coated tablet	Oral use
Sweden	Pfizer AB 191 90 Sollentuna Sweden	Lipitor	40mg	Film-coated tablet	Oral use
Sweden	Pfizer AB 191 90 Sollentuna Sweden	Lipitor	80 mg	Film-coated tablet	Oral use
United Kingdom	Pfizer Ireland Pharmaceuticals, Pottery Road, Dun Laoghaire, Co Dublin Ireland	Lipitor	10mg	Film-coated tablet	Oral use

Member State EU/EEA	**Marketing Authorisation Holder**	**Invented name Name**	**Strength**	**Pharmaceutical Form**	**Route of administration**
United Kingdom	Pfizer Ireland Pharmaceuticals, Pottery Road, Dun Laoghaire, Co Dublin Ireland	Lipitor	20mg	Film-coated tablet	Oral use
United Kingdom	Pfizer Ireland Pharmaceuticals, Pottery Road, Dun Laoghaire, Co Dublin Ireland	Lipitor	40mg	Film-coated tablet	Oral use
United Kingdom	Pfizer Ireland Pharmaceuticals, Pottery Road, Dun Laoghaire, Co Dublin Ireland	Lipitor	80 mg	Film-coated tablet	Oral use

ANNEX II

AMENDMENTS TO THE SUMMARY OF PRODUCT CHARACTERISTICS, LABELLING AND PACKAGE LEAFLET

These amendments to the SPC, labelling and package leaflet are valid at the time of the Commission Decision.

After the Commission Decision the Member State Competent Authorities will update the product information as required

AMENDMENTS TO BE INCLUDED IN THE RELEVANT SECTIONS OF THE SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

[See Annex I - To be completed nationally]
{PRODUCT NAME} 10 mg **chewable tablet**

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each **chewable tablet** contains 10 mg atorvastatin (as atorvastatin calcium (trihydrate)).

Excipients:

Each {PRODUCT NAME} 10 mg **chewable tablet contains 1.25 mg aspartame**.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Chewable tablet
White to off-white, round chewable tablets with pink to purple specks, debossed "10" on one side and "Pfizer" on the other measuring 7.1 mm in diameter.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Hypercholesterolaemia

{PRODUCT NAME} is indicated as an adjunct to diet for reduction of elevated total cholesterol, LDL-cholesterol, apolipoprotein B, and triglycerides in ~~patients~~ **adults, adolescents and children aged 10 years or older** with primary hypercholesterolaemia including familial hypercholesterolaemia (heterozygous variant) or combined (mixed) hyperlipidaemia (Corresponding to Types IIa and IIb of the Fredrickson classification) when response to diet and other nonpharmacological measures is inadequate.

{PRODUCT NAME} is also indicated to reduce total-C and LDL-C in ~~patients~~ **adults** with homozygous familial hypercholesterolaemia as an adjunct to other lipid-lowering treatments (e.g. LDL apheresis) or if such treatments are unavailable.

Prevention of cardiovascular disease

Prevention of cardiovascular events in adult patients estimated to have a high risk for a first cardiovascular event (see Section 5.1), as an adjunct to correction of other risk factors.

4.2 Posology and method of administration

{To be completed nationally}.

Paediatric use

~~Pediatric use should only be carried out by specialists.~~

~~Experience in pediatrics is limited to a small number of patients (age 4 - 17 years) with severe dyslipidemias, such as homozygous familial hypercholesterolemia. The recommended starting dose in this population is 10 mg of atorvastatin per day. The dose may be increased to 80 mg daily, according to the response and tolerability. Developmental safety data in this population have not been evaluated.~~

Hypercholesterolaemia:

Paediatric use should only be carried out by physicians experienced in the treatment of paediatric hyperlipidaemia and patients should be re-evaluated on a regular basis to assess progress.

For patients aged 10 years and above, the recommended starting dose of atorvastatin is 10 mg per day with titration up to 20 mg per day. Titration should be conducted according to the individual response and tolerability in paediatric patients. Safety information for paediatric patients treated with doses above 20 mg, corresponding to about 0.5 mg/kg, is limited.

There is limited experience in children between 6-10 years of age (see section 5.1). Atorvastatin is not indicated in the treatment of patients below the age of 10 years.

{PRODUCT NAME} tablets can be chewed or swallowed whole with a drink of water, and can be taken at any time of day, with or without food.

4.3 Contraindications

{To be completed nationally}.

4.4 Special warnings and precautions for use

{To be completed nationally}.

Paediatric use

Developmental safety in the paediatric population has not been established (see section 4.8).

~~Patients with rare hereditary problems of galactose intolerance, Lapp lactose deficiency or glucose-galactose malabsorption should not take this medicine.~~ **{PRODUCT NAME} chewable tablet contains aspartame which is a source of phenylalanine. May be harmful for people with phenylketonuria.**

4.5 Interaction with other medicinal products and other forms of interaction

{To be completed nationally}.

Paediatric population

Drug-drug interaction studies have only been performed in adults. The extent of interactions in the paediatric population is not known. The above mentioned interactions for adults and the warnings in section 4.4 should be taken into account for the paediatric population.

4.6 Pregnancy and lactation

{To be completed nationally}.

4.7 Effects on ability to drive and use machines

{To be completed nationally}.

4.8 Undesirable effects

{To be completed nationally}.

Paediatric Population

The clinical safety database includes safety data for 249 paediatric patients who received atorvastatin, among which 7 patients were < 6 years old, 14 patients were in the age range of 6 to 9, and 228 patients were in the age range of 10 to 17.

Nervous system disorders
Common: Headache

Gastrointestinal disorders
Common: Abdominal pain

Investigations
Common: Alanine aminotransferase increased, blood creatine phosphokinase increased

Based on the data available, frequency, type and severity of adverse reactions in children are expected to be the same as in adults. There is currently limited experience with respect to long-term safety in the paediatric population.

4.9 Overdose

{To be completed nationally}.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

{To be completed nationally}.

Paediatric Population

Heterozygous Familial Hypercholesterolaemia in Paediatric Patients aged 6-17 years old

An 8-week, open-label study to evaluate pharmacokinetics, pharmacodynamics, and safety and tolerability of atorvastatin was conducted in children and adolescents with genetically confirmed heterozygous familial hypercholesterolemia and baseline LDL-C ≥4 mmol/L. A total of 39 children and adolescents, 6 to 17 years of age, were enrolled. Cohort A included 15 children, 6 to 12 years of age and at Tanner Stage 1. Cohort B included 24 children, 10 to 17 years of age and at Tanner Stage ≥2.

The initial dose of atorvastatin was 5 mg daily of a chewable tablet in Cohort A and 10 mg daily of a tablet formulation in Cohort B. The atorvastatin dose was permitted to be doubled if a subject had not attained target LDL-C of <3.35 mmol/L at Week 4 and if atorvastatin was well tolerated.

Mean values for LDL-C, TC, VLDL-C, and Apo B decreased by Week 2 among all subjects. For subjects whose dose was doubled, additional decreases were observed as early as 2 weeks, at the first assessment, after dose escalation. The mean percent decreases in lipid parameters were similar for both cohorts, regardless of whether subjects remained at their initial dose or doubled their initial dose. At Week 8, on average, the percent change from baseline in LDL-C and TC was approximately 40% and 30%, respectively, over the range of exposures.

Heterozygous Familial Hypercholesterolaemia in Paediatric Patients aged 10-17 years old

In a double-blind, placebo controlled study followed by an open-label phase, 187 boys and postmenarchal girls 10-17 years of age (mean age 14.1 years) with heterozygous familial hypercholesterolaemia (FH) or severe hypercholesterolaemia were randomised to atorvastatin (n=140) or placebo (n=47) for 26 weeks and then all received atorvastatin for 26 weeks The dosage of atorvastatin (once daily) was 10 mg for the first 4 weeks and up-titrated to 20 mg if the LDL-C level was >3.36 mmol/l. Atorvastatin significantly decreased plasma levels of total-C, LDL-C, triglycerides, and apolipoprotein B during the 26 week double-blind phase. The mean achieved LDL-C value was 3.38 mmol/l (range: 1.81-6.26 mmol/l) in the atorvastatin group compared to 5.91 mmol/l (range: 3.93-9.96 mmol/l) in the placebo group during the 26-week double-blind phase.

An additional paediatric study of atorvastatin versus colestipol in patients with hypercholesterolaemia aged 10-18 years demonstrated that atorvastatin (N=25) caused a significant reduction in LDL-C at week 26 ($p<0.05$) compared with colestipol (N=31).

A compassionate use study in patients with severe hypercholesterolaemia (including homozygous hypercholesterolaemia) included 46 paediatric patients treated with atorvastatin titrated according to response (some subjects received 80 mg atorvastatin per day). The study lasted 3 years: LDL-cholesterol was lowered by 36%.

The long-term efficacy of atorvastatin therapy in childhood to reduce morbidity and mortality in adulthood has not been established.

The European Medicines Agency has waived the obligation to submit the results of studies with atorvastatin in children aged 0 to less than 6 years in the treatment of heterozygous hypercholesterolaemia and in children aged 0 to less than 18 years in the treatment of homozygous familial hypercholesterolaemia, combined (mixed) hypercholesterolaemia, primary hypercholesterolaemia and in the prevention of cardiovascular events (see section 4.2 for information on paediatric use).

5.2 Pharmacokinetic properties

{To be completed nationally}.

Special populations

{To be completed nationally}.

- Paediatric: ~~Pharmacokinetic data in the paediatric population are not available.~~ **In an open-label, 8-week study, Tanner Stage 1 (N=15) and Tanner Stage ≥2 (N=24) paediatric patients (ages 6-17 years) with heterozygous familial hypercholesterolemia and baseline LDL-C ≥4 mmol/L were treated with 5 or 10 mg of chewable or 10 or 20 mg of film-coated atorvastatin tablets once daily, respectively. Body weight was the only significant covariate in atorvastatin population PK model. Apparent oral clearance of atorvastatin in paediatric subjects appeared similar to adults when scaled allometrically by body weight. Consistent decreases in LDL-C and TC were observed over the range of atorvastatin and o-hydroxyatorvastatin exposures.**
- {To be completed nationally}.

5.3 Preclinical safety data

{To be completed nationally}.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium carbonate
Microcrystalline cellulose
Croscarmellose sodium
Polysorbate 80
Magnesium stearate
Hydroxypropyl cellulose
Amylum pregelificatum
Mannitol (E421)
Aspartame (E951)
Sucralose (E955)
Grape flavour

6.2 Incompatibilities

{To be completed nationally}.

6.3 Shelf life

24 months

6.4 Special precautions for storage

{To be completed nationally}.

6.5 Nature and contents of container

Blister packs containing 30 chewable tablets.

The blisters consist of a forming foil made of polyamide/aluminium foil/polyvinyl chloride and a backing made of aluminium foil/vinyl/acryl heat-seal coating.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

{To be completed nationally}.

7. MARKETING AUTHORISATION HOLDER

[To be completed nationally]

[See Annex I - 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

1. NAME OF THE MEDICINAL PRODUCT

[See Annex I - To be completed nationally]
{PRODUCT NAME} 20 mg **chewable tablet**

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each **chewable tablet** contains 20 mg atorvastatin (as atorvastatin calcium (trihydrate)).

Excipients:

Each {PRODUCT NAME} 20 mg **chewable tablet contains 2.5 mg aspartame**.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Chewable tablet
White to off-white, round chewable tablets with pink to purple specks debossed "20" on one side and "Pfizer" on the other measuring 8.7 mm in diameter.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Hypercholesterolaemia

{PRODUCT NAME} is indicated as an adjunct to diet for reduction of elevated total cholesterol, LDL-cholesterol, apolipoprotein B, and triglycerides in ~~patients~~ **adults, adolescents and children aged 10 years or older** with primary hypercholesterolaemia including familial hypercholesterolaemia (heterozygous variant) or combined (mixed) hyperlipidaemia (Corresponding to Types IIa and IIb of the Fredrickson classification) when response to diet and other nonpharmacological measures is inadequate.

{PRODUCT NAME} is also indicated to reduce total-C and LDL-C in ~~patients~~ **adults** with homozygous familial hypercholesterolaemia as an adjunct to other lipid-lowering treatments (e.g. LDL apheresis) or if such treatments are unavailable.

Prevention of cardiovascular disease

Prevention of cardiovascular events in adult patients estimated to have a high risk for a first cardiovascular event (see Section 5.1), as an adjunct to correction of other risk factors.

4.2 Posology and method of administration

{To be completed nationally}.

Paediatric use

~~Pediatric use should only be carried out by specialists.~~
~~Experience in pediatrics is limited to a small number of patients (age 4 - 17 years) with severe dyslipidemias, such as homozygous familial hypercholesterolemia. The recommended starting dose in~~

~~this population is 10 mg of atorvastatin per day. The dose may be increased to 80 mg daily, according to the response and tolerability. Developmental safety data in this population have not been evaluated.~~

Hypercholesterolaemia:

Paediatric use should only be carried out by physicians experienced in the treatment of paediatric hyperlipidaemia and patients should be re-evaluated on a regular basis to assess progress.

For patients aged 10 years and above, the recommended starting dose of atorvastatin is 10 mg per day with titration up to 20 mg per day. Titration should be conducted according to the individual response and tolerability in paediatric patients. Safety information for paediatric patients treated with doses above 20 mg, corresponding to about 0.5 mg/kg, is limited.

There is limited experience in children between 6-10 years of age (see section 5.1). Atorvastatin is not indicated in the treatment of patients below the age of 10 years.

{PRODUCT NAME} tablets can be chewed or swallowed whole with a drink of water, and can be taken at any time of day, with or without food.

4.3 Contraindications

{To be completed nationally}.

4.4 Special warnings and precautions for use

{To be completed nationally}.

Paediatric use

Developmental safety in the paediatric population has not been established (see section 4.8).

~~Patients with rare hereditary problems of galactose intolerance, Lapp lactose deficiency or glucose-galactose malabsorption should not take this medicine.~~ **{PRODUCT NAME} chewable tablet contains aspartame which is a source of phenylalanine. May be harmful for people with phenylketonuria.**

4.5 Interaction with other medicinal products and other forms of interaction

{To be completed nationally}.

Paediatric population

Drug-drug interaction studies have only been performed in adults. The extent of interactions in the paediatric population is not known. The above mentioned interactions for adults and the warnings in section 4.4 should be taken into account for the paediatric population.

4.6 Pregnancy and lactation

{To be completed nationally}.

4.7 Effects on ability to drive and use machines

{To be completed nationally}.

4.8 Undesirable effects

{To be completed nationally}.

Paediatric Population

The clinical safety database includes safety data for 249 paediatric patients who received atorvastatin, among which 7 patients were < 6 years old, 14 patients were in the age range of 6 to 9, and 228 patients were in the age range of 10 to 17.

Nervous system disorders
Common: Headache

Gastrointestinal disorders
Common: Abdominal pain

Investigations
Common: Alanine aminotransferase increased, blood creatine phosphokinase increased

Based on the data available, frequency, type and severity of adverse reactions in children are expected to be the same as in adults. There is currently limited experience with respect to long-term safety in the paediatric population.

4.9 Overdose

{To be completed nationally}.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

{To be completed nationally}.

Paediatric Population

Heterozygous Familial Hypercholesterolaemia in Paediatric Patients aged 6-17 years old

An 8-week, open-label study to evaluate pharmacokinetics, pharmacodynamics, and safety and tolerability of atorvastatin was conducted in children and adolescents with genetically confirmed heterozygous familial hypercholesterolemia and baseline LDL-C ≥4 mmol/L. A total of 39 children and adolescents, 6 to 17 years of age, were enrolled. Cohort A included 15 children, 6 to 12 years of age and at Tanner Stage 1. Cohort B included 24 children, 10 to 17 years of age and at Tanner Stage ≥2.

The initial dose of atorvastatin was 5 mg daily of a chewable tablet in Cohort A and 10 mg daily of a tablet formulation in Cohort B. The atorvastatin dose was permitted to be doubled if a subject had not attained target LDL-C of <3.35 mmol/L at Week 4 and if atorvastatin was well tolerated.

Mean values for LDL-C, TC, VLDL-C, and Apo B decreased by Week 2 among all subjects. For subjects whose dose was doubled, additional decreases were observed as early as 2 weeks, at the first assessment, after dose escalation. The mean percent decreases in lipid parameters were similar for both cohorts, regardless of whether subjects remained at their initial dose or doubled

their initial dose. At Week 8, on average, the percent change from baseline in LDL-C and TC was approximately 40% and 30%, respectively, over the range of exposures.

Heterozygous Familial Hypercholesterolaemia in Paediatric Patients aged 10-17 years old

In a double-blind, placebo controlled study followed by an open-label phase, 187 boys and postmenarchal girls 10-17 years of age (mean age 14.1 years) with heterozygous familial hypercholesterolaemia (FH) or severe hypercholesterolaemia were randomised to atorvastatin (n=140) or placebo (n=47) for 26 weeks and then all received atorvastatin for 26 weeks.. The dosage of atorvastatin (once daily) was 10 mg for the first 4 weeks and up-titrated to 20 mg if the LDL-C level was >3.36 mmol/l. Atorvastatin significantly decreased plasma levels of total-C, LDL-C, triglycerides, and apolipoprotein B during the 26 week double-blind phase. The mean achieved LDL-C value was 3.38 mmol/l (range: 1.81-6.26 mmol/l) in the atorvastatin group compared to 5.91 mmol/l (range: 3.93-9.96 mmol/l) in the placebo group during the 26-week double-blind phase.

An additional paediatric study of atorvastatin versus colestipol in patients with hypercholesterolaemia aged 10-18 years demonstrated that atorvastatin (N=25) caused a significant reduction in LDL-C at week 26 ($p<0.05$) compared with colestipol (N=31).

A compassionate use study in patients with severe hypercholesterolaemia (including homozygous hypercholesterolaemia) included 46 paediatric patients treated with atorvastatin titrated according to response (some subjects received 80 mg atorvastatin per day). The study lasted 3 years: LDL-cholesterol was lowered by 36%.

The long-term efficacy of atorvastatin therapy in childhood to reduce morbidity and mortality in adulthood has not been established.

The European Medicines Agency has waived the obligation to submit the results of studies with atorvastatin in children aged 0 to less than 6 years in the treatment of heterozygous hypercholesterolaemia and in children aged 0 to less than 18 years in the treatment of homozygous familial hypercholesterolaemia, combined (mixed) hypercholesterolaemia, primary hypercholesterolaemia and in the prevention of cardiovascular events (see section 4.2 for information on paediatric use).

5.2 Pharmacokinetic properties

{To be completed nationally}.

Special populations

{To be completed nationally}.

- Paediatric: ~~Pharmacokinetic data in the paediatric population are not available.~~ **In an open-label, 8-week study, Tanner Stage 1 (N=15) and Tanner Stage ≥2 (N=24) paediatric patients (ages 6-17 years) with heterozygous familial hypercholesterolemia and baseline LDL-C ≥4 mmol/L were treated with 5 or 10 mg of chewable or 10 or 20 mg of film-coated atorvastatin tablets once daily, respectively. Body weight was the only significant covariate in atorvastatin population PK model. Apparent oral clearance of atorvastatin in paediatric subjects appeared similar to adults when scaled allometrically by body weight. Consistent decreases in LDL-C and TC were observed over the range of atorvastatin and o-hydroxyatorvastatin exposures.**
- {To be completed nationally}.

5.3 Preclinical safety data

{To be completed nationally}.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium carbonate
Microcrystalline cellulose
Croscarmellose sodium
Polysorbate 80
Magnesium stearate
Hydroxypropyl cellulose
Amylum pregelificatum
Mannitol (E421)
Aspartame (E951)
Sucralose (E955)
Grape flavour

6.2 Incompatibilities

{To be completed nationally}.

6.3 Shelf life

24 months

6.4 Special precautions for storage

{To be completed nationally}.

6.5 Nature and contents of container

Blister packs containing 30 chewable tablets.

The blisters consist of a forming foil made of polyamide/aluminium foil/polyvinyl chloride and a backing made of aluminium foil/vinyl/acryl heat-seal coating.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

{To be completed nationally}.

7. MARKETING AUTHORISATION HOLDER

[To be completed nationally]

[See Annex I - 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

1. NAME OF THE MEDICINAL PRODUCT

[See Annex I - To be completed nationally]
{PRODUCT NAME} 40 mg **chewable tablet**

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each **chewable tablet** contains 40 mg atorvastatin (as atorvastatin calcium (trihydrate)).

Excipients:

Each {PRODUCT NAME} 40 mg **chewable tablet contains 5 mg aspartame**.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Chewable tablet
White to off-white, round chewable tablets with pink to purple specks, debossed "40" on one side and "Pfizer" on the other measuring 10.3 mm in diameter.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Hypercholesterolaemia

{PRODUCT NAME} is indicated as an adjunct to diet for reduction of elevated total cholesterol, LDL-cholesterol, apolipoprotein B, and triglycerides in ~~patients~~ **adults, adolescents and children aged 10 years or older** with primary hypercholesterolaemia including familial hypercholesterolaemia (heterozygous variant) or combined (mixed) hyperlipidaemia (Corresponding to Types IIa and IIb of the Fredrickson classification) when response to diet and other nonpharmacological measures is inadequate.

{PRODUCT NAME} is also indicated to reduce total-C and LDL-C in ~~patients~~ **adults** with homozygous familial hypercholesterolaemia as an adjunct to other lipid-lowering treatments (e.g. LDL apheresis) or if such treatments are unavailable.

Prevention of cardiovascular disease

Prevention of cardiovascular events in adult patients estimated to have a high risk for a first cardiovascular event (see Section 5.1), as an adjunct to correction of other risk factors.

4.2 Posology and method of administration

{To be completed nationally}.

Paediatric use

~~Pediatric use should only be carried out by specialists.~~
~~Experience in pediatrics is limited to a small number of patients (age 4 - 17 years) with severe dyslipidemias, such as homozygous familial hypercholesterolemia. The recommended starting dose in~~

~~this population is 10 mg of atorvastatin per day. The dose may be increased to 80 mg daily, according to the response and tolerability. Developmental safety data in this population have not been evaluated.~~

Hypercholesterolaemia:

Paediatric use should only be carried out by physicians experienced in the treatment of paediatric hyperlipidaemia and patients should be re-evaluated on a regular basis to assess progress.

For patients aged 10 years and above, the recommended starting dose of atorvastatin is 10 mg per day with titration up to 20 mg per day. Titration should be conducted according to the individual response and tolerability in paediatric patients. Safety information for paediatric patients treated with doses above 20 mg, corresponding to about 0.5 mg/kg, is limited.

There is limited experience in children between 6-10 years of age (see section 5.1). Atorvastatin is not indicated in the treatment of patients below the age of 10 years.

{PRODUCT NAME} tablets can be chewed or swallowed whole with a drink of water, and can be taken at any time of day, with or without food.

4.3 Contraindications

{To be completed nationally}.

4.4 Special warnings and precautions for use

{To be completed nationally}.

Paediatric use

Developmental safety in the paediatric population has not been established (see section 4.8).

~~Patients with rare hereditary problems of galactose intolerance, Lapp lactose deficiency or glucose-galactose malabsorption should not take this medicine.~~ **{PRODUCT NAME} chewable tablet contains aspartame which is a source of phenylalanine. May be harmful for people with phenylketonuria.**

4.5 Interaction with other medicinal products and other forms of interaction

{To be completed nationally}.

Paediatric population

Drug-drug interaction studies have only been performed in adults. The extent of interactions in the paediatric population is not known. The above mentioned interactions for adults and the warnings in section 4.4 should be taken into account for the paediatric population.

4.6 Pregnancy and lactation

{To be completed nationally}.

4.7 Effects on ability to drive and use machines

{To be completed nationally}.

4.8 Undesirable effects

{To be completed nationally}.

Paediatric Population

The clinical safety database includes safety data for 249 paediatric patients who received atorvastatin, among which 7 patients were < 6 years old, 14 patients were in the age range of 6 to 9, and 228 patients were in the age range of 10 to 17.

Nervous system disorders
Common: Headache

Gastrointestinal disorders
Common: Abdominal pain

Investigations
Common: Alanine aminotransferase increased, blood creatine phosphokinase increased

Based on the data available, frequency, type and severity of adverse reactions in children are expected to be the same as in adults. There is currently limited experience with respect to long-term safety in the paediatric population.

4.9 Overdose

{To be completed nationally}.

5.0 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

{To be completed nationally}.

Paediatric Population

Heterozygous Familial Hypercholesterolaemia in Paediatric Patients aged 6-17 years old

An 8-week, open-label study to evaluate pharmacokinetics, pharmacodynamics, and safety and tolerability of atorvastatin was conducted in children and adolescents with genetically confirmed heterozygous familial hypercholesterolemia and baseline LDL-C ≥4 mmol/L. A total of 39 children and adolescents, 6 to 17 years of age, were enrolled. Cohort A included 15 children, 6 to 12 years of age and at Tanner Stage 1. Cohort B included 24 children, 10 to 17 years of age and at Tanner Stage ≥2.

The initial dose of atorvastatin was 5 mg daily of a chewable tablet in Cohort A and 10 mg daily of a tablet formulation in Cohort B. The atorvastatin dose was permitted to be doubled if a subject had not attained target LDL-C of <3.35 mmol/L at Week 4 and if atorvastatin was well tolerated.

Mean values for LDL-C, TC, VLDL-C, and Apo B decreased by Week 2 among all subjects. For subjects whose dose was doubled, additional decreases were observed as early as 2 weeks, at the first assessment, after dose escalation. The mean percent decreases in lipid parameters were similar for both cohorts, regardless of whether subjects remained at their initial dose or doubled

their initial dose. At Week 8, on average, the percent change from baseline in LDL-C and TC was approximately 40% and 30%, respectively, over the range of exposures.

Heterozygous Familial Hypercholesterolaemia in Paediatric Patients aged 10-17 years old

In a double-blind, placebo controlled study followed by an open-label phase, 187 boys and postmenarchal girls 10-17 years of age (mean age 14.1 years) with heterozygous familial hypercholesterolaemia (FH) or severe hypercholesterolaemia were randomised to atorvastatin (n=140) or placebo (n=47) for 26 weeks and then all received atorvastatin for 26 weeks. The dosage of atorvastatin (once daily) was 10 mg for the first 4 weeks and up-titrated to 20 mg if the LDL-C level was >3.36 mmol/l. Atorvastatin significantly decreased plasma levels of total-C, LDL-C, triglycerides, and apolipoprotein B during the 26 week double-blind phase. The mean achieved LDL-C value was 3.38 mmol/l (range: 1.81-6.26 mmol/l) in the atorvastatin group compared to 5.91 mmol/l (range: 3.93-9.96 mmol/l) in the placebo group during the 26-week double-blind phase.

An additional paediatric study of atorvastatin versus colestipol in patients with hypercholesterolaemia aged 10-18 years demonstrated that atorvastatin (N=25) caused a significant reduction in LDL-C at week 26 ($p<0.05$) compared with colestipol (N=31).

A compassionate use study in patients with severe hypercholesterolaemia (including homozygous hypercholesterolaemia) included 46 paediatric patients treated with atorvastatin titrated according to response (some subjects received 80 mg atorvastatin per day). The study lasted 3 years: LDL-cholesterol was lowered by 36%.

The long-term efficacy of atorvastatin therapy in childhood to reduce morbidity and mortality in adulthood has not been established.

The European Medicines Agency has waived the obligation to submit the results of studies with atorvastatin in children aged 0 to less than 6 years in the treatment of heterozygous hypercholesterolaemia and in children aged 0 to less than 18 years in the treatment of homozygous familial hypercholesterolaemia, combined (mixed) hypercholesterolaemia, primary hypercholesterolaemia and in the prevention of cardiovascular events (see section 4.2 for information on paediatric use).

5.2 Pharmacokinetic properties

{To be completed nationally}.

Special populations

{To be completed nationally}.

- Paediatric: ~~Pharmacokinetic data in the paediatric population are not available.~~ **In an open-label, 8-week study, Tanner Stage 1 (N=15) and Tanner Stage ≥2 (N=24) paediatric patients (ages 6-17 years) with heterozygous familial hypercholesterolemia and baseline LDL-C ≥4 mmol/L were treated with 5 or 10 mg of chewable or 10 or 20 mg of film-coated atorvastatin tablets once daily, respectively. Body weight was the only significant covariate in atorvastatin population PK model. Apparent oral clearance of atorvastatin in paediatric subjects appeared similar to adults when scaled allometrically by body weight. Consistent decreases in LDL-C and TC were observed over the range of atorvastatin and o-hydroxyatorvastatin exposures.**
- {To be completed nationally}.

5.3 Preclinical safety data

{To be completed nationally}.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium carbonate
Microcrystalline cellulose
Croscarmellose sodium
Polysorbate 80
Magnesium stearate
Hydroxypropyl cellulose
Amylum pregelificatum
Mannitol (E421)
Aspartame (E951)
Sucralose (E955)
Grape flavour

6.2 Incompatibilities

{To be completed nationally}.

6.3 Shelf life

24 months

6.4 Special precautions for storage

{To be completed nationally}.

6.5 Nature and contents of container

Blister packs containing 30 chewable tablets.

The blisters consist of a forming foil made of polyamide/aluminium foil/polyvinyl chloride and a backing made of aluminium foil/vinyl /acryl heat-seal coating.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

{To be completed nationally}.

7. MARKETING AUTHORISATION HOLDER

[To be completed nationally]

[See Annex I - 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

AMENDMENTS TO BE INCLUDED IN THE RELEVANT SECTIONS OF THE LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON

1. NAME OF THE MEDICINAL PRODUCT

{PRODUCT NAME} 10 mg chewable tablets
Atorvastatin

2. STATEMENT OF ACTIVE SUBSTANCE(S)

1 chewable tablet contains 10 mg atorvastatin (as calcium salt trihydrate).

3. LIST OF EXCIPIENTS

Contains aspartame. See package leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

30 chewable 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

[To be completed nationally].

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

16. INFORMATION IN BRAILLE

{PRODUCT NAME} 10 mg chewable tablets

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

BLISTERS

1. NAME OF THE MEDICINAL PRODUCT

{PRODUCT NAME} 10 mg chewable tablets
Atorvastatin

2. NAME OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]
{Name}

3. EXPIRY DATE

EXP:

4. BATCH NUMBER

Batch:

5. OTHER

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON

1. NAME OF THE MEDICINAL PRODUCT

{PRODUCT NAME} 20 mg chewable tablets
Atorvastatin

2. STATEMENT OF ACTIVE SUBSTANCE(S)

1 chewable tablet contains 20 mg atorvastatin (as calcium salt trihydrate).

3. LIST OF EXCIPIENTS

Contains aspartame. See package leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

30 chewable 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

[To be completed nationally].

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

16. INFORMATION IN BRAILLE

{PRODUCT NAME} 20 mg chewable tablets

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

BLISTERS

1. NAME OF THE MEDICINAL PRODUCT

{PRODUCT NAME} 20 mg chewable tablets
Atorvastatin

2. NAME OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]
{Name}

3. EXPIRY DATE

EXP:

4. BATCH NUMBER

Batch:

5. OTHER

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON

1. NAME OF THE MEDICINAL PRODUCT

{PRODUCT NAME} 40 mg chewable tablets
Atorvastatin

2. STATEMENT OF ACTIVE SUBSTANCE(S)

1 chewable tablet contains 40 mg atorvastatin (as calcium salt trihydrate).

3. LIST OF EXCIPIENTS

Contains aspartame. See package leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

30 chewable 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

[To be completed nationally].

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

16. INFORMATION IN BRAILLE

{PRODUCT NAME} 40 mg chewable tablets

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

BLISTERS

1. NAME OF THE MEDICINAL PRODUCT

{PRODUCT NAME} 40 mg chewable tablets
Atorvastatin

2. NAME OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]
{Name}

3. EXPIRY DATE

EXP:

4. BATCH NUMBER

Batch:

5. OTHER

AMENDMENTS TO BE INCLUDED IN THE RELEVANT SECTIONS OF THE PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

{PRODUCT NAME} 10 mg chewable tablets
Atorvastatin calcium
[See Annex I - To be completed nationally]

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 {PRODUCT NAME} IS AND WHAT IT IS USED FOR

{To be completed nationally}.

2. BEFORE YOU TAKE {PRODUCT NAME}

{To be completed nationally}.

Important information about some of the ingredients of {PRODUCT NAME}
~~If youhave been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.~~ **Contains a source of phenylalanine. May be harmful for people with phenylketonuria.**

3. HOW TO TAKE {PRODUCT NAME}

The usual starting dose of {PRODUCT NAME} is 10 mg once a day **in adults and children aged 10 years or older**. This may be increased if necessary by your doctor until you are taking the amount you need. Your doctor will adapt the dosage at intervals of 4 weeks or more. The maximum dose of {PRODUCT NAME}is 80 mg once daily **for adults and 20 mg once daily for children.**

{PRODUCT NAME} tablets **can be chewed or** ~~should be~~ swallowed whole with a drink of water, and can be taken at any time of day, with or without food. However, try to take your tablet at the same time every day.

{To be completed nationally}.

4. POSSIBLE SIDE EFFECTS

{To be completed nationally}.

5. HOW TO STORE {PRODUCT NAME}

{To be completed nationally}.

Do not use {PRODUCT NAME} after the expiry date {EXP:} which is stated on the **blister** ~~container~~ and outer packaging. The expiry date refers to the last day of that month.

{To be completed nationally}.

6. FURTHER INFORMATION

What {PRODUCT NAME} contains
The active substance of {PRODUCT NAME} is atorvastatin. Each tablet contains 10 mg of atorvastatin as atorvastatin calcium trihydrate.

{PRODUCT NAME} tablets also contain the inactive ingredients: **calcium carbonate, microcrystalline cellulose, croscarmellose sodium, polysorbate 80, hydroxypropyl cellulose, amylum pregelificatum, mannitol, aspartame, sucralose, grape flavour and magnesium stearate**.

What {PRODUCT NAME} looks like and contents of the pack
{PRODUCT NAME} **10 mg chewable tablets are white to off-white with pink to purple specks with a round shape. They are marked with 10 on one side and Pfizer on the other side.**

{PRODUCT NAME} are available in blister packs containing **30 chewable tablets.**

This medicine is available as 5 mg, 10 mg, 20 mg and 40 mg chewable tablets and 10 mg, 20 mg, 40 mg and 80 mg film-coated tablets.

Marketing Authorisation Holder and Manufacturer

{Name and address}
<{tel}>
<{fax}>
<{e-mail}>

[See Annex I - To be completed nationally]

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

{To be completed nationally}.

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

[To be completed nationally]

PACKAGE LEAFLET: INFORMATION FOR THE USER

{PRODUCT NAME} 20 mg chewable tablets
Atorvastatin calcium
[See Annex I - To be completed nationally]

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 {PRODUCT NAME} IS AND WHAT IT IS USED FOR

{To be completed nationally}.

2. BEFORE YOU TAKE {PRODUCT NAME}

{To be completed nationally}.

Important information about some of the ingredients of {PRODUCT NAME}
~~If youhave been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.~~ **Contains a source of phenylalanine. May be harmful for people with phenylketonuria.**

3. HOW TO TAKE {PRODUCT NAME}

The usual starting dose of {PRODUCT NAME} is 10 mg once a day **in adults and children aged 10 years or older**. This may be increased if necessary by your doctor until you are taking the amount you need. Your doctor will adapt the dosage at intervals of 4 weeks or more. The maximum dose of {PRODUCT NAME}is 80 mg once daily **for adults and 20 mg once daily for children.**

{PRODUCT NAME} tablets **can be chewed or** ~~should be~~ swallowed whole with a drink of water, and can be taken at any time of day, with or without food. However, try to take your tablet at the same time every day.

{To be completed nationally}.

4. POSSIBLE SIDE EFFECTS

{To be completed nationally}.

5. HOW TO STORE {PRODUCT NAME}

{To be completed nationally}.

Do not use {PRODUCT NAME} after the expiry date {EXP:} which is stated on the **blister** ~~container~~ and outer packaging. The expiry date refers to the last day of that month.

{To be completed nationally}.

6. FURTHER INFORMATION

What {PRODUCT NAME} contains
The active substance of {PRODUCT NAME} is atorvastatin. Each tablet contains 20 mg of atorvastatin as atorvastatin calcium trihydrate.

{PRODUCT NAME} tablets also contain the inactive ingredients: **calcium carbonate, microcrystalline cellulose, croscarmellose sodium, polysorbate 80, hydroxypropyl cellulose, amylum pregelificatum, mannitol, aspartame, sucralose, grape flavour and magnesium stearate**.

What {PRODUCT NAME} looks like and contents of the pack
{PRODUCT NAME} **20 mg chewable tablets are white to off-white with pink to purple specks with a round shape. They are marked with 20 on one side and Pfizer on the other side.**

{PRODUCT NAME} are available in blister packs containing **30 chewable tablets.**

This medicine is available as 5 mg, 10 mg, 20 mg and 40 mg chewable tablets and 10 mg, 20 mg, 40 mg and 80 mg film-coated tablets.

Marketing Authorisation Holder and Manufacturer

{Name and address}
<{tel}>
<{fax}>
<{e-mail}>

[See Annex I - To be completed nationally]

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

{To be completed nationally}.

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

[To be completed nationally]

PACKAGE LEAFLET: INFORMATION FOR THE USER

{PRODUCT NAME} 40 mg chewable tablets
Atorvastatin calcium
[See Annex I - To be completed nationally]

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 {PRODUCT NAME} IS AND WHAT IT IS USED FOR

{To be completed nationally}.

2. BEFORE YOU TAKE {PRODUCT NAME}

{To be completed nationally}.

Important information about some of the ingredients of {PRODUCT NAME}
~~If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.~~ **Contains a source of phenylalanine. May be harmful for people with phenylketonuria.**

3. HOW TO TAKE {PRODUCT NAME}

The usual starting dose of {PRODUCT NAME} is 10 mg once a day **in adults and children aged 10 years or older**. This may be increased if necessary by your doctor until you are taking the amount you need. Your doctor will adapt the dosage at intervals of 4 weeks or more. The maximum dose of {PRODUCT NAME}is 80 mg once daily **for adults and 20 mg once daily for children.**

{PRODUCT NAME} tablets **can be chewed or** ~~should be~~ swallowed whole with a drink of water, and can be taken at any time of day, with or without food. However, try to take your tablet at the same time every day.

{To be completed nationally}.

4. POSSIBLE SIDE EFFECTS

{To be completed nationally}.

5. HOW TO STORE {PRODUCT NAME}

{To be completed nationally}.

Do not use {PRODUCT NAME} after the expiry date {EXP:} which is stated on the **blister** ~~container~~ and outer packaging. The expiry date refers to the last day of that month.

{To be completed nationally}.

6. FURTHER INFORMATION

What {PRODUCT NAME} contains
The active substance of {PRODUCT NAME} is atorvastatin. Each tablet contains 40 mg of atorvastatin as atorvastatin calcium trihydrate.

{PRODUCT NAME} tablets also contain the inactive ingredients: **calcium carbonate, microcrystalline cellulose, croscarmellose sodium, polysorbate 80, hydroxypropyl cellulose, amylum pregelificatum, mannitol, aspartame, sucralose, grape flavour and magnesium stearate**.

What {PRODUCT NAME} looks like and contents of the pack
{PRODUCT NAME} **40 mg chewable tablets are white to off-white with pink to purple specks with a round shape. They are marked with 40 on one side and Pfizer on the other side.**

{PRODUCT NAME} are available in blister packs containing **30 chewable tablets.**

This medicine is available as 5 mg, 10 mg, 20 mg and 40 mg chewable tablets and 10 mg, 20 mg, 40 mg and 80 mg film-coated tablets.

Marketing Authorisation Holder and Manufacturer

{Name and address}
<{tel}>
<{fax}>
<{e-mail}>

[See Annex I - To be completed nationally]

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

{To be completed nationally}.

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

[To be completed nationally]

ANNEX III

CONDITIONS OF THE MARKETING AUTHORISATION

The National Health Authorities shall ensure the following conditions are fulfilled by the Marketing Authorisation Holder:

- Submit a Risk Management Plan (or its update) for Sortis and associated names at National level, taking into account the new paediatric data and the CHMP recommendations. The Risk Management Plan should include the ongoing study A2581173 (3-year study of the safety and follow-up study of efficacy of atorvastatin treatment of children and adolescents aged 6 years to less than 18 years with heterozygous familial hypercholesterolaemia).

- Restart the cycle of PSUR submission for Sortis and associated names as follows:
    - Six-monthly PSURs until two full years of experience with the paediatric indication in the EU has been gained
    - Yearly PSURs for the following two years
    - Thereafter submission at 3-yearly intervals

  The PSURs should focus on the use in the paediatric population.