



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 February 2013
EMA/124076/2013
Patient Health Protection

Annex I

List of the names, pharmaceutical forms, strengths of the medicinal products, routes of administration, marketing authorisation holders in the member states for codeine containing medicinal products used for pain in children

Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data

Procedure number: EMEA/H/A-31/1342

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Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Austria	Mundipharma GmbH, Apollogasse 16 - 18 1070 Vienna Austria	Codidol retard 60 mg - Filmtabletten	Dihydrocodeine	60 mg	prolonged- release tablet	oral use
Austria	Mundipharma GmbH, Apollogasse 16 - 18 1070 Vienna Austria	Codidol retard 90 mg - Filmtabletten	Dihydrocodeine	90 mg	prolonged- release tablet	oral use
Austria	Mundipharma GmbH, Apollogasse 16 - 18 1070 Vienna Austria	Codidol retard 120 mg - Filmtabletten	Dihydrocodeine	120 mg	prolonged- release tablet	oral use
Austria	G.L. Pharma GmbH, Schloßplatz 1 8502 Lannach Austria	Dehace retard 60 mg - Filmtabletten	Dihydrocodeine	60 mg	prolonged- release tablet	oral use
Austria	G.L. Pharma GmbH, Schloßplatz 1 8502 Lannach Austria	Dehace retard 90 mg - Filmtabletten	Dihydrocodeine	90 mg	prolonged- release tablet	oral use
Austria	G.L. Pharma GmbH, Schloßplatz 1 8502 Lannach Austria	Dehace retard 120 mg - Filmtabletten	Dihydrocodeine	120 mg	prolonged- release tablet	oral use
Belgium	Laboratoires SMB SA rue de la Pastorale 26- 28 1080 Brussels Belgium	Algocod	Paracetamol/ Codeine phosphate hemihydrate	500 mg/30 mg	effervescent tablet	oral use
Belgium	Laboratoires SMB SA rue de la Pastorale 26- 28 1080 Brussels Belgium	Algocod	Paracetamol/ Codeine phosphate hemihydrate	500 mg/30 mg	powder for oral solution	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Belgium	Bristol-Meyers Squibb Belgium sa Chaussée de la Hulpe 185 1170 Brussels Belgium	Dafalgan codeine	Paracetamol/ Codeine phosphate hemihydrate	500 mg/30 mg	effervescent tablet	oral use
Belgium	Bristol-Meyers Squibb Belgium sa Chaussée de la Hulpe 185 1170 Brussels Belgium	Dafalgan codeine	Paracetamol/ Codeine phosphate hemihydrate	500 mg/30 mg	film-coated tablet	oral use
Belgium	Aktuapharma nv Ambachtenlaan 13E 3001 Leuven Belgium	Dafalgan codeine	Paracetamol/ Codeine phosphate hemihydrate	500 mg/30 mg	tablet	oral use
Belgium	Sterop Laboratoires nv Avenue de Scheut 46- 50 1070 Brussels Belgium	Nevrine codeine	Paracetamol Caffeine Codeine phosphate hemihydrate	500 mg 50 mg 30 mg	tablet	oral use
Belgium	Glaxosmithkline Consumer Healthcare sa Site Apollo, Avenue 2-4-6, 1300 Wavre Belgium	Panadol codeine	Paracetamol/ Codeine phosphate hemihydrate	500 mg/30 mg	tablet	oral use
Belgium	Teva Pharma Belgium Laarstraat 16 2610 Wilrijk Belgium	Paracetamol codeine teva	Paracetamol/ Codeine phosphate hemihydrate	500 mg/30 mg	dispersible tablet	oral use
Belgium	Mylan BVBA/SPRL Terhulpesteenweg 6A, B-1560 Hoeilaart Belgium	Paracodmylan	Paracetamol/ Codeine phosphate hemihydrate	500 mg/30 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Bulgaria	Actavis EAD 29 Atanas Dukov Str. Sofia 1407 Bulgaria	Aceffein	Acetylsalicylic acid/ Caffeine/ Codeine phosphate/ Paracetamol	250 mg/50 mg/ 10 mg/ 250 mg	tablet	oral use
Bulgaria	Mundipharma Ges.m.b.H Apollogasse 16-18 Vienna 1072 Austria	DHC Continus	Dihydrocodeine tartrate	60 mg	modified-release tablet	oral use
Bulgaria	Mundipharma Ges.m.b.H Apollogasse 16-18 Vienna 1072 Austria	DHC Continus	Dihydrocodeine tartrate	90 mg	modified-release tablet	oral use
Bulgaria	Unipharm JSC Traiko Stanoev str. № 3 Sofia 1797 Bulgaria	Paracofdal	Metamizole sodium/ Paracetamol/ Caffeine/ Codeine phosphate	300 mg/ 200 mg/ 30 mg/20 mg	tablet	oral use
Bulgaria	GlaxoSmithKline Export Ltd 980 Great West Road Brentford Middlesex TW8 9GS United Kingdom	Solpadeine	Paracetamol/ Codeine Phosphate Hemihydrate/ Caffeine	500 mg/ 8 mg/ 30 mg	soluble tablet	oral use
Bulgaria	GlaxoSmithKline Export Ltd 980 Great West Road Brentford Middlesex TW8 9GS United Kingdom	Solpadeine	Paracetamol/ Codeine Phosphate Hemihydrate/ Caffeine	500 mg/ 8 mg/ 30 mg	capsule, hard	oral use
Cyprus	Multi-Pharm Co Ltd, 22 Philopimenos Str, P.O.Box 59522 Lemesos 4010 Cyprus	TALVOSILEN TABLET	Paracetamol/ Codeine phosphate	500mg/20mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Cyprus	Multi-Pharm Co Ltd, 22 Philopimenos Str, P.O.Box 59522 Lemesos 4010 Cyprus	TALVOSILEN FORTE SUPPOSITORY	Paracetamol/ Codeine phosphate	1000mg/60mg	suppository	rectal use
Cyprus	Multi-Pharm Co Ltd, 22 Philopimenos Str, P.O.Box 59522 Lemesos 4010 Cyprus	TALVOSILEN FORTE TABLET	Paracetamol/ Codeine phosphate	500mg/30mg	tablet	oral use
Cyprus	C A Papaellina & Co Ltd 179 Yiannos Kranidiotis ave., P.O.Box 24018 Lefkosia 2235 Cyprus	SOLPADEINE SOLUBLE TABLET	Paracetamol/ Codeine Phosphate Hemihydrate/ Caffeine	500mg/8mg/30mg	effervescent tablet	oral use
Cyprus	C A Papaellina & Co Ltd 179 Yiannos Kranidiotis ave., P.O.Box 24018 Lefkosia 2235 Cyprus	SOLPADEINE TABLET	Paracetamol/ Codeine Phosphate Hemihydrate/ Caffeine	500mg/8mg/30mg	tablet	oral use
Cyprus	Aegis Ltd, 17 Athinon Street, Ergates Industrial Area, P.O.Box 28629 Lefkosia Cyprus	PARCOTEN TABLET	Paracetamol/ Codeine phosphate	500mg/10mg	tablet	oral use
Cyprus	Boehringer Ingelheim Hellas SA 2 Ellinikou Str 16777, Elliniko, Athens Greece	LONARID N SUPPOSITORY	Paracetamol+ caffeine+ codeine phosphate hemihydrate	(400+50+20)mg	suppository	rectal use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Cyprus	Boehringer Ingelheim Hellas SA 2 Ellinikou Str 16777, Elliniko, Athens Greece	LONARID N TABLET	Paracetamol+ caffeine+ codeine phosphate hemihydrate	(400+50+10)mg	tablet	oral use
Cyprus	Mundipharma Pharmaceuticals Ltd, 13 Othellos Str, Dhali Industrial Zone P.O.Box 23661 Lefkosia Cyprus	CODANOL TABLET	Paracetamol/ Dihydrocodeine	500mg/20mg	tablet	oral use
Cyprus	Mundipharma Pharmaceuticals Ltd, 13 Othellos Str, Dhali Industrial Zone P.O.Box 23661 Lefkosia Cyprus	DHC CONTINUS PROLONGED RELEASE TABLETS 60MG	Dihydrocodeine tartare	60 mg	prolonged-release tablet	oral use
Czech Republic	Zentiva a.s. Nitrianska 100 920 27 Hlohovec Slovak Republic	CODEIN SLOVAKOFARMA 15 MG	Codeini phosphas hemihydricus	15 mg	tablet	oral use
Czech Republic	Zentiva a.s. Nitrianska 100 920 27 Hlohovec Slovak Republic	CODEIN SLOVAKOFARMA 30 MG	Codeini phosphas hemihydricus	30 mg	tablet	oral use
Czech Republic	Zentiva, k.s. U kabelovny 130 102 37 Praha 10 Czech Republic	KORYLAN	Codeini phosphas hemihydricus + paracetamolium	28,73 mg + 325 mg	tablet	oral use
Czech Republic	Zentiva, k.s. U kabelovny 130 102 37 Praha 10 Czech Republic	ULTRACOD	Codeini phosphas hemihydricus + paracetamolium	30 mg + 500 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Czech Republic	bene-Arzneimittel GmbH Herterichstrasse 1 814 79 München Germany	TALVOSILEN	Codeini phosphas sesquihydricus + paracetamolium	20 mg + 500 mg	tablet	oral use
Czech Republic	bene-Arzneimittel GmbH Herterichstrasse 1 814 79 München Germany	TALVOSILEN FORTE	Codeini phosphas hemihydricus + paracetamolium	30 mg + 500 mg	capsule, hard	oral use
Czech Republic	GlaxoSmithKline Consumer Healthcare, GlaxoSmithKline Export Ltd. Great West Road 980 Brentford TW8 9GS United Kingdom	PANADOL ULTRA	Codeini phosphas hemihydricus + paracetamolium + coffeinum	8 mg + 500 mg + 30 mg	tablet	oral use
Czech Republic	GlaxoSmithKline Consumer Healthcare, GlaxoSmithKline Export Ltd. Great West Road 980 Brentford TW8 9GS United Kingdom	PANADOL ULTRA RAPIDE	Codeini phosphas hemihydricus + paracetamolium + coffeinum	8 mg + 500 mg + 30 mg	effervescent tablet	oral use
Czech Republic	Zentiva, k.s. U kabelovny 130 102 37 Praha 10 - Dolní Měcholupy Czech Republic	SPASMOPAN	Codeini phosphas hemihydricus + paracetamolium + pitofenoni hydrochloridum + fempiverinii bromidum	19,2 mg + 500 mg + 10 mg + 0,1 mg	suppository	rectal use
Denmark	Alternova A/S, Lodshusvej 11, DK-4230 Skælskør, Denmark	Kodein "Alternova"	Codeine	25 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Denmark	Nycomed Danmark ApS, Langebjerg 1, DK-4000 Roskilde Denmark	Kodein "DAK"	Codeine	25 mg	film-coated tablet	oral use
Denmark	Nycomed Danmark ApS, Langebjerg 1, DK-4000 Roskilde Denmark	Kodein "DAK"	Codeine	3 mg/ml	oral solution	oral use
Denmark	Nycomed Danmark ApS, Langebjerg 1, DK-4000 Roskilde Denmark	Kodimagnyl "DAK"	ASA + codeine	500 mg + 10 mg	effervescent tablet	oral use
Denmark	Nycomed Danmark ApS, Langebjerg 1, DK-4000 Roskilde Denmark	Kodein Stærk "DAK"	Codeine	8 mg/ml	oral solution	oral use
Denmark	Nycomed Danmark ApS, Langebjerg 1, DK-4000 Roskilde Denmark	Kodimagnyl "DAK"	ASA + codeine	500 mg + 9,6 mg	tablet	oral use
Denmark	Nycomed Danmark ApS, Langebjerg 1, DK-4000 Roskilde Denmark	Kodimagnyl Ikke-stoppende "DAK"	ASA + codeine	500 mg + 9,6 mg	film-coated tablet	oral use
Denmark	Nycomed Danmark ApS, Langebjerg 1, DK-4000 Roskilde Denmark	Kodipar	Codeine + paracetamol	30,6 mg + 500 mg	film-coated tablet	oral use
Denmark	Amgros I/S, Dampfærgevej 22, DK-2100 København Ø, Denmark	Kodein "SAD"	Codeine	25 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Estonia	GlaxoSmithKline Export Ltd 980 Great West Road Brentford Middlesex TW8 9GS United Kingdom	SOLPADEINE SOLUBLE	Paracetamol/Codeine/Caffeine	500 mg/8 mg/30 mg	effervescent tablet	oral use
Estonia	Zentiva, k.s. U Kabelovny 130 Dolni Mecholupy 102 37 Prague 10 Czech Republic	ALGOCALM	Codeine/Paracetamol	30mg/500mg	tablet	oral use
Estonia	GlaxoSmithKline Export Ltd 980 Great West Road Brentford Middlesex TW8 9GS United Kingdom	SOLPADEINE	Paracetamol/Codeine/Caffeine	500 mg/8 mg/30 mg	tablet	oral use
Estonia	Vitabalans Oy Varastokatu 8, 13500 Hämeenlinna Finland	PARACETAMOL/CODEINE VITABALANS	Codeine/Paracetamol	30mg/500mg	tablet	oral use
Estonia	Actavis UK Limited Whiddon Valley, Barnstaple, Devon, EX32 8NS United Kingdom	CO-CODAMOL	Paracetamol/Codeine	500mg/8mg	tablet	oral use
Finland	Ratiopharm Oy PL 67 02631 Espoo Finland	CODAXOL	Codeine phosphate Paracetamol	30 mg 500 mg	tablet	oral use
Finland	Oy Leiras Finland Ab Paciuksenkatu 21 PL 1406 00101 Helsinki Finland	PAMOL COD	Codeine phosphate Paracetamol	30 mg 500 mg	effervescent tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Finland	Sanofi-aventis Oy Huopalahdentie 24 PL 22 00351 Helsinki Finland	PANACOD	Codeine phosphate Paracetamol	30 mg 500 mg	tablet	oral use
Finland	Sanofi-aventis Oy Huopalahdentie 24 PL 22 00351 Helsinki Finland	PANACOD	Codeine phosphate Paracetamol	30 mg 500 mg	effervescent tablet	oral use
Finland	Bene-Arzneimittel GmbH Herterichstrasse 1 81479 München Germany	PARACETAMOL/CODEIN BENE.ARZNEIMITTEL	Codeine phosphate Paracetamol	30 mg 500 mg	tablet	oral use
Finland	Vitabalans Oy Varastokatu 8 13500 Hämeenlinna Finland	PARAMAX-COD	Codeine phosphate Paracetamol	30 mg 500 mg	tablet	oral use
France	EG LABO - Laboratoires EuroGenerics "Le Quintet" - bâtiment A 12, rue Danjou 92517 Boulogne Billancourt Cedex France	PARACETAMOL CODEINE EG 500 mg/30 mg, comprimé effervescent sécable	Paracetamol/Codeine	500 mg/30 mg	effervescent tablet	oral use
France	Societe Cilfa Developpement 20, Rue Jean Daudin 75015 – Paris France	SEDARENE, gélule	Paracetamol/Codeine	300 mg/10 mg	capsule	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
France	Sanofi-Aventis France 1-13, Boulevard Romain Rolland 75014 Paris France	CODOLIPRANE ADULTES 400 mg/20 mg, comprimé sécable	Paracetamol/Codeine	400 mg/20 mg	tablet	oral use
France	Bayer Sante Familiale 33, Rue De L'industrie 74240 Gaillard France	CLARADOL CODEINE 500 mg/20 mg, comprimé	Paracetamol/Codeine	500 mg/20 mg	tablet	oral use
France	Sanofi-Aventis France 1-13, Boulevard Romain Rolland 75014 Paris France	CODOLIPRANE ENFANTS 400 mg/20 mg, comprimé sécable	Paracetamol/Codeine	400 mg/20 mg	tablet	oral use
France	Sanofi-Aventis France 1-13, Boulevard Romain Rolland 75014 Paris France	CODOLIPRANE 500 mg/30 mg, comprimé effervescent sécable	Paracetamol/Codeine	500 mg/30 mg	effervescent tablet	oral use
France	Pierre Fabre Medicament 45, Place Abel Gance 92654 Boulogne Cedex France	KLIPAL CODEINE 600 mg/50 mg, comprimé	Paracetamol/Codeine	600 mg/50 mg	tablet	oral use
France	Bouchara Recordati 68, Rue Marjolin Bp 67 92302 Levallois-Perret Cedex France	CODENFAN 1 mg/ml, sirop	Codeine	1 mg/ml	syrup	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
France	Arrow Generiques 26, avenue Tony Garnier 69007 Lyon France	PARACETAMOL CODEINE ARROW 500 mg/30 mg, comprimé effervescent sécable	Paracetamol/Codeine	500 mg/30 mg	effervescent tablet	oral use
France	Gifrer Barbezat 8 10, Rue Paul Bert Bp 165 69151 Décines Cedex France	COMPRALGYL 400 mg/20 mg, comprimé sécable	Paracetamol/Codeine	400 mg/20 mg	tablet	oral use
France	Pierre Fabre Medicament 45, Place Abel Gance 92654 Boulogne Cedex France	KLIPAL CODEINE 300 mg/25 mg, comprimé	Paracetamol/Codeine	300 mg/25 mg	tablet	oral use
France	Teva Sante 110, Esplanade du Général de Gaulle 92931 Paris La Défense Cedex France	PARACETAMOL CODEINE TEVA 500 mg/30 mg, comprimé effervescent sécable	Paracetamol/Codeine	500 mg/30 mg	effervescent tablet	oral use
France	Sanofi-Aventis France 1-13, Boulevard Romain Rolland 75014 Paris France	PARACETAMOL CODEINE SANOFI-AVENTIS FRANCE 500 mg/30 mg, comprimé effervescent sécable	Paracetamol/Codeine	500 mg/30 mg	effervescent tablet	oral use
France	SANDOZ 49, avenue Georges Pompidou 92300 Levallois-Perret France	PARACETAMOL CODEINE SANDOZ 500 mg/30 mg, comprimé effervescent sécable	Paracetamol/Codeine	500 mg/30 mg	effervescent tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
France	Biogaran 15, boulevard Charles de Gaulle 92700 Colombes France	PARACETAMOL CODEINE ALMUS 500 mg/30 mg, comprimé effervescent sécable	Paracetamol/Codeine	500 mg/30 mg	effervescent tablet	oral use
France	Cristers 22 quai Gallieni 92150 Suresnes France	PARACETAMOL CODEINE CRISTERS 500 mg/30 mg, comprimé effervescent sécable	Paracetamol/Codeine	500 mg/30 mg	effervescent tablet	oral use
France	Biogaran 15, boulevard Charles de Gaulle 92700 Colombes France	PARACETAMOL CODEINE BIOGARAN 500 mg/30 mg, comprimé effervescent sécable	Paracetamol/Codeine	500 mg/30 mg	effervescent tablet	oral use
France	Mylan Sas 117, allée des Parcs 69800 Saint-Priest France	PARACETAMOL CODEINE MYLAN 500 mg/30 mg, comprimé effervescent sécable	Paracetamol/Codeine	500 mg/30 mg	effervescent tablet	oral use
France	Bristol Myers Squibb - 3, rue Joseph Monier 92500 Rueil-Malmaison France	DAFALGAN CODEINE, comprimé effervescent sécable	Paracetamol/Codeine	500 mg/30 mg	effervescent tablet	oral use
France	Bristol Myers Squibb - 3, rue Joseph Monier 92500 Rueil-Malmaison France	DAFALGAN CODEINE, comprimé pelliculé	Paracetamol/Codeine	500 mg/30 mg	coated tablet	oral use
France	Elaiapharm 2881, Route des Crêtes BP 205 Valbonne 06904 Sophia Antipolis Cedex France	COPRALGIR 400 mg/20 mg, comprimé sécable	Paracetamol/Codeine	400 mg/20 mg	coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
France	Merck Medication Familiale 37, rue Saint-Romain 69379 Lyon Cedex 08 France	GAOSEDAL CODEINE, comprimé	Paracetamol/Codeine	500 mg/20 mg	tablet	oral use
France	Meda Pharma (France) 25 boulevard de l'amiral bruix 75016 Paris France	ALGISEDAL, comprimé	Paracetamol/Codeine	400 mg/25 mg,	tablet	oral use
France	Pharmastra 2c, rue du marchal de l'atire de tassigny 67460 Souffelweyersheim France	NOVACETOL (ASPIRINE PARACETAMOL), comprimé	Codeine (Chlorhydrate de) /acétylsalicylique (acide)/ paracétamol/paracétamol granulé 96	10,0 mg / 300,0 mg/187,5 mg/ 65,1 mg	tablet	oral use
Germany	ALIUD PHARMA GmbH Gottlieb-Daimler-Str. 19 89150 Laichingen Germany	Paracetamol AL comp.	codeinphosphat- hemihydrat paracetamol	30 mg 500 mg	tablet	oral use
Germany	Aristo Pharma GmbH Wallenroder Str. 8-10 13435 Berlin Germany	Azur compositum	codeinphosphat- hemihydrat coffein paracetamol	40 mg 50 mg 600 mg	suppository	rectal use
Germany	Aristo Pharma GmbH Wallenroder Str. 8-10 13435 Berlin Germany	Azur compositum	codeinphosphat- hemihydrat coffein paracetamol	30 mg 50 mg 350 mg	tablet	oral use
Germany	Aristo Pharma GmbH Wallenroder Str. 8-10 13435 Berlin Germany	Azur compositum SC	codeinphosphat- hemihydrat paracetamol	30 mg 500 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Germany	Aristo Pharma GmbH Wallenroder Str. 8-10 13435 Berlin Germany	Azur compositum SC Suppositorien	codeinphosphat- hemihydrat paracetamol	60 mg 1000 mg	suppository	rectal use
Germany	Astellas Pharma GmbH Georg-Brauchle-Ring 64-66 80992 München Germany	Dolomo TN	codeinphosphat- hemihydrat paracetamol acetylsalicylsäure coffein	30 mg 250 mg 250 mg 50 mg	tablet	oral use
Germany	bene - Arzneimittel GmbH Herterichstr. 1 - 3 81479 München Germany	Paracetamol/Codein 500 mg/30 mg bene	codeinphosphat- hemihydrat paracetamol	30 mg 500 mg	suppository	rectal use
Germany	bene - Arzneimittel GmbH Herterichstr. 1 - 3 81479 München Germany	talvosilen	codeinphosphat- hemihydrat paracetamol	20 mg 500 mg	tablet	oral use
Germany	bene - Arzneimittel GmbH Herterichstr. 1 - 3 81479 München Germany	talvosilen	codeinphosphat- hemihydrat paracetamol	20 mg 500 mg	capsule	oral use
Germany	bene - Arzneimittel GmbH Herterichstr. 1 - 3 81479 München Germany	talvosilen 1000 mg/20 mg Zäpfchen	codeinphosphat- hemihydrat paracetamol	20 mg 1000 mg	suppository	rectal use
Germany	bene - Arzneimittel GmbH Herterichstr. 1 - 3 81479 München Germany	talvosilen 250 mg/5 mg Zäpfchen	codeinphosphat- hemihydrat paracetamol	5 mg 250 mg	suppository	rectal use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Germany	bene - Arzneimittel GmbH Herterichstr. 1 - 3 81479 München Germany	talvosilen 500 mg/10 mg Zäpfchen	codeinphosphat- hemihydrat paracetamol	10 mg 500 mg	suppository	rectal use
Germany	bene - Arzneimittel GmbH Herterichstr. 1 - 3 81479 München Germany	talvosilen 500 mg/30 mg	codeinphosphat- hemihydrat paracetamol	30 mg 500 mg	suppository	rectal use
Germany	bene - Arzneimittel GmbH Herterichstr. 1 - 3 81479 München Germany	talvosilen forte	codeinphosphat- hemihydrat paracetamol	30 mg 500 mg	capsule, hard	oral use
Germany	bene - Arzneimittel GmbH Herterichstr. 1 - 3 81479 München Germany	talvosilen forte	codeinphosphat- hemihydrat paracetamol	60 mg 1000 mg	suppository	rectal use
Germany	bene - Arzneimittel GmbH Herterichstr. 1 - 3 81479 München Germany	talvosilen forte	codeinphosphat- hemihydrat paracetamol	30 mg 500 mg	tablet	oral use
Germany	bene - Arzneimittel GmbH Herterichstr. 1 - 3 81479 München Germany	talvosilen-Saft	codeinphosphat- hemihydrat paracetamol	5 mg/5ml 200 mg/5ml	suspension	oral use
Germany	Berlin-Chemie AG Glienicke Weg 125 12489 Berlin Germany	Codeinum phosphoricum Berlin-Chemie	codeinphosphat- hemihydrat	30 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Germany	Berlin-Chemie AG Glienicke Weg 125 12489 Berlin Germany	Titretta Schmerztabletten	codeinphosphat-hemihydrat paracetamol	30 mg 500 mg	tablet	oral use
Germany	Berlin-Chemie AG Glienicke Weg 125 12489 Berlin Germany	Titretta Zäpfchen 1000/60	codeinphosphat-hemihydrat paracetamol	60 mg 1000 mg	suppository	rectal use
Germany	Dr. R. Pflieger Chemische Fabrik GmbH Dr.-Robert-Pflieger-Str. 12 96052 Bamberg Germany	Contraneural Paracetamol/Codein	codeinphosphat-hemihydrat paracetamol	30 mg 500 mg	tablet	oral use
Germany	Dr. R. Pflieger Chemische Fabrik GmbH Dr.-Robert-Pflieger-Str. 12 96052 Bamberg Germany	Contraneural Paracetamol/Codein 500 mg/30 mg	codeinphosphat-hemihydrat paracetamol	30 mg 500 mg	tablet	oral use
Germany	Dr. R. Pflieger Chemische Fabrik GmbH Dr.-Robert-Pflieger-Str. 12 96052 Bamberg Germany	Optipyrin	codeinphosphat-hemihydrat paracetamol	60 mg 1000 mg	suppository	rectal use
Germany	MEDA Manufacturing GmbH Neurather Ring 1 51063 Köln Germany	Dolviran N	codeinphosphat-hemihydrat acetylsalicylsäure	30 mg 500 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Germany	Merck Serono GmbH Alsfelder Str. 17 64289 Darmstadt Germany	Nedolon P	codeinphosphat- hemihydrat paracetamol	30 mg 500 mg	tablet	oral use
Germany	Novartis Pharma GmbH Roonstr. 25 90429 Nürnberg Germany	Combaren 50 mg/50 mg Filmtabletten	codeinphosphat- hemihydrat diclofenac-natrium	50 mg 50 mg	film-coated tablet	oral use
Germany	Novartis Pharma GmbH Roonstr. 25 90429 Nürnberg Germany	Voltaren Plus 50 mg/50 mg Filmtabletten	codeinphosphat- hemihydrat diclofenac-natrium	50 mg 50 mg	film-coated tablet	oral use
Germany	OPTIMED Pharma GmbH Alfred-Nobel-Str. 5 50226 Frechen Germany	codi OPT	codeinphosphat- hemihydrat	60 mg	tablet	oral use
Germany	Pfizer Pharma GmbH Linkstr. 10 10785 Berlin Germany	Gelonida Schmerztabletten	codeinphosphat- hemihydrat paracetamol	30 mg 500 mg	tablet	oral use
Germany	Stadapharm GmbH Stadastr. 2 - 18 61118 Bad Vilbel Germany	Paracetamol comp. STADA 500 mg/30 mg	codeinphosphat- hemihydrat paracetamol	30 mg 500 mg	tablet	oral use
Germany	Temmler Werke GmbH Weihenstephaner Str. 28 81673 München Germany	Dolomo N	codeinphosphat- hemihydrat acetylsalicylsäure paracetamol	30 mg 250 mg 250 mg	tablet	oral use
Greece	Boehringer Ingelheim Hellas SA 2 Ellinikou Str 16777, Elliniko, Athens Greece	LONARID-N	Paracetamol+ Caffeine+ Codeine phosphate hemihydrate	(400+50+20)mg	suppository	rectal use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Greece	Boehringer Ingelheim Hellas SA 2 Ellinikou Str 16777, Elliniko, Athens Greece	LONARID-N	Paracetamol+ Caffeine+ Codeine phosphate hemihydrate	(400+50+10)mg	tablet	oral use
Greece	Boehringer Ingelheim Hellas SA 2 Ellinikou Str 16777, Elliniko, Athens Greece	LONALGAL	Paracetamol+ Codeine phosphate hemihydrate	(1000+30)mg	suppository	rectal use
Greece	Boehringer Ingelheim Hellas SA 2 Ellinikou Str 16777, Elliniko, Athens Greece	LONALGAL	Paracetamol+ Codeine phosphate hemihydrate	(500+30)mg	tablet	oral use
Iceland	Actavis Group hf. - Reykjavikurvegur 76-78 - 220 Hafnarfjörður Iceland	Pinex Comp Forte	Paracetamolum INN/Codeini Phosphas Hemihydricus	500 mg/30 mg	suppository	rectal use
Ireland	The Boots Company Plc, 1 Thane Road West, NG2 3AA, Nottingham United Kingdom	Ibuprofen and Codeine 200 mg/ 12.8 mg film-coated Tablets	Ibuprofen/Codeine Phosphate Hemihydrate	200 mg/ 12.8 mg	film-coated tablet	oral use
Ireland	Clonmel Healthcare Ltd, Waterford Road, Conmel, Co. Tipperary Ireland	Maxilief Effervescent Tablets Paracetamol 500mg Codeine Phosphate Hemihydrate 8mg Caffeine 30mg	Paracetamol, Codeine Phosphate Hemihydrate, Caffeine	500mg, 500mg, 8mg	effervescent tablet	oral use
Ireland	Sanofi-Aventis Ireland Limited, Citywest Business Campus, Dublin 24 Ireland	Solpadol Caplets 500 mg/30 mg Tablets.	Paracetamol Codeine Phosphate Hemihydrate	499 mg 30 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Ireland	Sanofi-Aventis Ireland Limited, Citywest Business Campus, Dublin 24 Ireland	Solpadol 500 mg/30 mg Effervescent Tablets	Paracetamol Codeine Phosphate Hemihydrate	500 mg 30 mg	effervescent tablet	oral use
Ireland	GlaxoSmithKline Consumer Healthcare (Ireland) Limited, Stonemasons Way, Rathfarnham, Dublin 16 Ireland	Panadeine Tablets Paracetamol 500mg Codeine Phosphate Hemihydrate 8mg	Paracetamol Codeine Phosphate Hemihydrate	500mg 8mg	tablet	oral use
Ireland	GlaxoSmithKline Consumer Healthcare (Ireland) Limited, Stonemasons Way, Rathfarnham, Dublin 16 Ireland	Panadeine Extra Strength Tablets Paracetamol 500 mg Codeine Phosphate hemihydrate 12.8 mg	Paracetamol Codeine Phosphate Hemihydrate	500mg 12.8mg	film-coated tablet	oral use
Ireland	GlaxoSmithKline Consumer Healthcare (Ireland) Limited, Stonemasons Way, Rathfarnham, Dublin 16 Ireland	Solpadeine Capsules Paracetamol 500mg Codeine Phosphate Hemihydrate 8mg Caffeine 30mg	Paracetamol Codeine Phosphate Hemihydrate Caffeine	500mg 8mg 30mg	capsule, hard	oral use
Ireland	GlaxoSmithKline Consumer Healthcare (Ireland) Limited, Stonemasons Way, Rathfarnham, Dublin 16 Ireland	Solpadeine Soluble Tablets Paracetamol 500mg Codeine Phosphate Hemihydrate 8mg Caffeine 30mg	Paracetamol Codeine Phosphate Hemihydrate Caffeine	500mg 8mg 30mg	effervescent tablet	oral use
Ireland	GlaxoSmithKline Consumer Healthcare (Ireland) Limited, Stonemasons Way, Rathfarnham, Dublin 16 Ireland	Solpadeine Tablets Paracetamol 500mg, Codeine Phosphate Hemihydrate 8mg, Caffeine 30mg	Paracetamol Codeine Phosphate Hemihydrate Caffeine	500mg 8mg 30mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Ireland	GlaxoSmithKline Consumer Healthcare (Ireland) Limited, Stonemasons Way, Rathfarnham, Dublin 16 Ireland	Apfen Plus 200mg / 12.8mg Film-Coated Tablets	Ibuprofen Codeine Phosphate Hemihydrate	200mg 12.8mg	film-coated tablet	oral use
Ireland	McNeil Healthcare (Ireland) Ltd, Airton Road, Tallaght, Dublin 24 Ireland	Migravele Pink Film-coated Tablets. Paracetamol 500mg Codeine Phosphate 8mg Buclizine Hydrochloride 6.25mg	Paracetamol Codeine Phosphate Buclizine Hydrochloride	500mg 8mg 6.25mg	film-coated tablet	oral use
Ireland	McNeil Healthcare (Ireland) Ltd, Airton Road, Tallaght, Dublin 24 Ireland	Migravele Yellow Film-coated Tablets Paracetamol 500mg Codeine phosphate 8mg	Paracetamol Codeine Phosphate	500mg 8mg	film-coated tablet	oral use
Ireland	McNeil Healthcare (Ireland) Ltd, Airton Road, Tallaght, Dublin 24 Ireland	Migravele Film-coated Tablets	Paracetamol Codeine Phosphate Buclizine Hydrochloride	500mg 8mg 6.25mg	film-coated tablet	oral use
Ireland	UCB (Pharma) Ireland Limited, United Drug House, Magna Drive, Magna Business Park, Citywest Road, Dublin 24 Ireland	Tylox 30 mg / 500 mg Hard Capsules	Paracetamol Codeine Phosphate Hemihydrate	500mg 30mg	capsule, hard	oral use
Ireland	UCB (Pharma) Ireland Limited, United Drug House, Magna Drive, Magna Business Park, Citywest Road, Dublin 24 Ireland	Tylox 30 mg / 500 mg Effervescent Tablets.	Paracetamol Codeine Phosphate Hemihydrate	500mg 30mg	effervescent tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Ireland	Reckitt Benckiser Ireland Ltd, 7 Riverwalk, Citywest Business Campus, Dublin 24 Ireland	Nurofen Plus Tablets Ibuprofen 200mg Codeine Phosphate Hemihydrate 12.8mg	Ibuprofen Codeine Phosphate Hemihydrate	200mg 12.8mg	film-coated tablet	oral use
Ireland	SSL International plc, 103-105 Bath Road, Slough, Berkshire, SL1 3UH, United Kingdom	Syndol Film-coated Tablets Paracetamol 450 mg Codeine Phosphate Hemihydrate 10 mg Doxylamine succinate 5 mg Caffeine 30 mg	Paracetamol Codeine phosphate hemihydrate Doxylamine succinate Caffeine	450 mg 10 mg 5 mg 30 mg	film-coated tablet	oral use
Ireland	Chefaro Ireland Limited, First Floor, Block A, The Crescent Building, Northwood Office Park, Dublin 9, Ireland	Veganin Plus Tablets	Paracetamol Codeine Phosphate Caffeine	500mg 8mg 30mg	film-coated tablet	oral use
Ireland	Galen Limited, Seogoe Industiral Estate, Craigavon BT 63 5 UA, United Kingdom	Kapake 15mg/500mg Tablets	Paracetamol Codeine Phosphate hemihydrate	500mg 15mg	tablet	oral use
Ireland	Galen Limited, Seogoe Industiral Estate, Craigavon BT 63 5 UA United Kingdom	Kapake 30mg/500mg Tablets	Paracetamol Codeine phosphate	500mg 30mg	tablet	oral use
Ireland	Bayer Limited, The Atrium, Blackthorn Road, Dublin 18, Ireland	Feminax Tablets	Paracetamol Codeine Phosphate Hyoscine Hydrobromide Anhydrous caffeine	500mg 8mg 100 micrograms 50 mg	tablet	oral use
Italy	Bristol-Myers Squibb S.A.R.L. 3 Rue Joseph Monier 92500 Rueil Malmaison France	CO EFFERELGAN	paracetamol + codeine phosphate	500mg + 30mg	effervescent tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Italy	Bristol-Myers Squibb S.A.R.L. 3 Rue Joseph Monier 92500 Rueil Malmaison France	CO EFFERELGAN	paracetamol + codeine phosphate	500mg + 30mg	film-coated tablet	oral use
Italy	Abiogen Pharma S.p.A. Via Meucci, 36 56014 Loc. Ospedaletto - Pisa Italy	CODAMOL	paracetamol + codeine phosphate	500mg + 30mg	effervescent tablet	oral use
Italy	BOEHRINGER INGELHEIM ITALIA S.P.A. Via Lorenzini, 8 20139 Milano Italy	LONARID	paracetamol + codeine phosphate	400mg + 10mg	tablet	oral use
Italy	BOEHRINGER INGELHEIM ITALIA S.P.A. Via Lorenzini, 8 20139 Milano Italy	LONARID	paracetamol + codeine phosphate	400mg + 20mg	suppository	rectal use
Italy	BOEHRINGER INGELHEIM ITALIA S.P.A. Via Lorenzini, 8 20139 Milano Italy	LONARID	paracetamol + codeine phosphate	200mg + 5mg	suppository	rectal use
Italy	Aziende Chimiche Riunite Angelini Francesco ACRAF S.p.A. Viale Amelia 70 00181 Roma Italy	TACHIDOL	paracetamol + codeine phosphate	500mg + 30mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Italy	Aziende Chimiche Riunite Angelini Francesco ACRAF S.p.A. Viale Amelia 70 00181 Roma Italy	TACHIDOL	paracetamol + codeine phosphate	500mg + 30mg	effervescent tablet	oral use
Italy	Aziende Chimiche Riunite Angelini Francesco ACRAF S.p.A. Viale Amelia 70 00181 Roma Italy	TACHIDOL	paracetamol + codeine phosphate	125 mg + 7,5 mg	effervescent granules	oral use
Italy	Aziende Chimiche Riunite Angelini Francesco ACRAF S.p.A. Viale Amelia 70 00181 Roma Italy	TACHIDOL	paracetamol + codeine phosphate	125/5 ml mg + 7,5/5 ml mg	syrup	oral use
Italy	Aziende Chimiche Riunite Angelini Francesco ACRAF S.p.A. Viale Amelia 70 00181 Roma Italy	TACHIDOL	paracetamol + codeine phosphate	500mg + 30mg	film-coated tablet	oral use
Italy	LABORATORI ALTER S.R.L. Via Egadi, 7 20144 Milano Italy	PARACETAMOLO E CODEINA ALTER	paracetamol + codeine phosphate	500mg + 30mg	effervescent tablet	oral use
Italy	Angenerico S.p.a. Via Nocera Umbra, 75 00181 Roma Italy	'PARACETAMOLO + CODEINA ANGENERICO	paracetamol + codeine	500mg + 30mg	effervescent granules	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Italy	Angenerico S.p.a. Via Nocera Umbra, 75 00181 Roma Italy	'PARACETAMOLO + CODEINA ANGENERICO	paracetamol + codeine	125 mg + 7,5 mg	effervescent granules	oral use
Italy	Angenerico S.p.a. Via Nocera Umbra, 75 00181 Roma Italy	'PARACETAMOLO + CODEINA ANGENERICO	paracetamol + codeine	25 mg/ml + 1,5 mg/ml	syrup	oral use
Latvia	ZENTIVA, k.s., U Kabelovny 130, Dolní Měcholupy, 102 37 Praha 10, The Czech Republic	Ultracod 500 mg/30 mg tablets	Paracetamolium/Codeini phosphas hemihydricus	500 mg/30 mg	tablet	oral use
Latvia	Actavis UK Ltd., Whiddon Valley, Barnstaple, N Devon, EX32 8NS United Kingdom	Co-Codamol 500 mg/8 mg tablets	Paracetamolium/Codeini phosphas hemihydricus	500 mg/8 mg	tablet	oral use
Latvia	GlaxoSmithKline Consumer Healthcare, GlaxoSmithKline Export Limited, Brentford, TW 8 9GS, United Kingdom	Solpadeine Soluble 500 mg/8 mg/30 mg soluble tablets	Paracetamolium/Codeini phosphas hemihydricus/Coffeinum	500 mg/8 mg/30 mg	soluble tablet	oral use
Latvia	GlaxoSmithKline Consumer Healthcare, GlaxoSmithKline Export Limited, Brentford, TW 8 9GS, United Kingdom	Solpadeine 500 mg/8 mg/30 mg tablets	Paracetamolium/Codeini phosphas hemihydricus/Coffeinum	500 mg/8 mg/30 mg	tablet	oral use
Lithuania	ZENTIVA, k.s., U Kabelovny 130, Dolní Měcholupy, 102 37 Praha 10, The Czech Republic	Ultracod	Paracetamol/Codeine phosphate hemihydrate	500mg/30mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Lithuania	GlaxoSmithKline Consumer Healthcare GlaxoSmithKline ExportLtd Brentford TW8 9GS United Kingdom	Solpadeine	Paracetamol/Codeine/Caf feine	500mg/8mg/30mg	soluble tablet	oral use
Lithuania	GlaxoSmithKline Consumer Healthcare GlaxoSmithKline ExportLtd Brentford TW8 9GS United Kingdom	Solpadeine	Paracetamol/Codeine/Caf feine	500mg/8mg/30mg	tablet	oral use
Luxembourg	MEDA PHARMA 25 boulevard de l'amiral Bruix F-75016 Paris France	Algisedal	Paracetamol/Codeine phosphate hemihydrate	400mg/25mg	tablet	oral use
Luxembourg	Laboratoires SMB S.A. Rue de la Pastorale 26- 28 B 1080 Bruxelles Belgium	Algocod	Paracetamol/Codeine phosphate hemihydrate	500mg/30mg	effervescent tablet	oral use
Luxembourg	Laboratoires SMB S.A. Rue de la Pastorale 26- 28 B 1080 Bruxelles Belgium	Algocod	Paracetamol/Codeine phosphate hemihydrate	500mg/30mg	powder	oral use
Luxembourg	Bristol-Myers Squibb Belgium S.A. Avenue de Finlande, 8 B-1420 Braine-l'Alleud Belgium	Dafalgan codéine	Paracetamol/Codeine phosphate hemihydrate	500mg/30mg	film-coated tablet	oral use
Luxembourg	Bristol-Myers Squibb Belgium S.A. Avenue de Finlande, 8 B-1420 Braine-l'Alleud Belgium	Dafalgan codéine	Paracetamol/Codeine phosphate hemihydrate	500mg/30mg	effervescent tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Luxembourg	Meda Pharma GmbH&Co. KG Benzstr.1 D-61352 Bad Homburg Germany	Dolviran N	Aspirin/Codeine phosphate hemihydrate	500mg/30mg	tablet	oral use
Luxembourg	GlaxoSmithKline Consumer Healthcare S.A. Site Apollo avenue Pascal 2-6 B-1300 Wavre Belgium	Panadol codéine	Paracetamol/Codeine phosphate hemihydrate	500mg/30mg	tablet	oral use
Luxembourg	Mylan bvba/sprl Rozendal Businesspark Terhulpesteenweg 6A B-1560 Hoeilaart Belgium	Paracod Mylan	Paracetamol/Codeine phosphate	500mg /30mg	dispersible tablet	oral use
Luxembourg	bene-Arzneimittel GmbH Herterichstraße 1-3 D-81479 München Germany	Talvosilen forte 500/30	Paracetamol/Codeine phosphate hemihydrate	500mg/30mg	tablet	oral use
Luxembourg	bene-Arzneimittel GmbH Herterichstraße 1-3 D-81479 München Germany	Talvosilen forte 1000/60	Paracetamol/Codeine phosphate hemihydrate	1000mg/60 mg	suppository	rectal use
Malta	Wockhardt UK Ltd., Ash Road North Wrexham, LL13 9 UF, United Kingdom	Codeine Phosphate 30mg Tablets	Codeine phosphate	30mg	tablet	oral use
Malta	Seton Products Ltd., Tubiton House, Medlock Street, Oldham, OL1 3HS, United Kingdom	Syndol	Paracetamol Codeine Phosphate Doxylamine succinate Caffeine	450mg 10mg 5mg 30mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Malta	Crookes Healthcare Ltd 1 Thane Road West Nottingham NG2 3AA United Kingdom	Nurofen Plus	Ibuprofen Codeine phosphate	200.0mg 12.8mg	tablet	oral use
Malta	GlaxoSmithKline Consumer Healthcare (Ireland) Limited Stonemasons Way Rathfarnham Dublin 16 Ireland	Solpadeine Soluble Tablets	Paracetamol Codeine Phosphate Hemihydrate Caffeine	500mg 8mg 30mg	effervescent tablet	oral use
Malta	SmithKline Beecham (SWG) Limited 980 Great West Road Brentford Middlesex TW8 9GS United Kingdom Trading as Sterling Health or GlaxoSmithKline Consumer Healthcare or SmithKline Beecham International, Brentford, TW8 9GS United Kingdom	Solpadeine Plus Capsules	Paracetamol Codeine Phosphate Hemihydrate Caffeine	500mg 8mg 30mg	capsule, hard	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Malta	SmithKline Beecham (SWG) Limited 980 Great West Road Brentford Middlesex TW8 9GS United Kingdom Trading as Sterling Health or GlaxoSmithKline Consumer Healthcare or SmithKline Beecham International, Brentford, TW8 9GS.	Solpadeine Migraine Ibuprofen & Codeine Tablets	Ibuprofen Codeine phosphate hemihydrate	200.0 mg 12.8 mg	film-coated tablet	oral use
Malta	McNeil Products Ltd., Foundation Park, Roxborough Way, Maidenhead, Berkshire SL6 3UG United Kingdom	Migravele	<u>Migravele Pink Tablets:</u> Paracetamol, codeine phosphate, buclizine hydrochloride <u>Migravele Yellow Tablets:</u> Paracetamol, codeine phosphate	<u>Migravele Pink Tablets:</u> 520mg, 8mg, 6.25mg <u>Migravele Yellow Tablets:</u> 520mg, 8mg	film-coated tablet	oral use
Malta	McNeil Products Ltd., Foundation Park, Roxborough Way, Maidenhead, Berkshire SL6 3UG United Kingdom	Migravele Yellow	Paracetamol/codeine phosphate	520mg/8mg	film-coated tablet	oral use
Malta	M&A Pharmachem Limited, Allenby Laboratories, Wigan Road, Westhoughton Bolton BL5 2AL United Kingdom	Co-Codamol Tablets BP 8/500mg	Paracetamol/codeine phosphate	500mg/8mg	tablet	oral use
Norway	Vitabalans Oy, Varastokatu 8, 13500 Hameenlinna Finland.	Paramax Comp	Paracetamol/ Codein phosphate hemihydrate	500 mg/30 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Norway	ratiopharm Oy- Teva Group Member, Keilaranta 10 E, 02150 Espoo, Finland	Codaxol	Paracetamol/ Codein phosphate hemihydrate	500 mg/30 mg	tablet	oral use
Norway	Actavis Group hf. - Reykjavikurvegur 76-78 - 220 Hafnarfjörður Iceland	Pinex Forte	Paracetamol/ Codein phosphate hemihydrate	500 mg/30 mg	effervescent tablet	oral use
Norway	Actavis Group hf. - Reykjavikurvegur 76-78 - 220 Hafnarfjörður Iceland	Pinex Forte	Paracetamol/ Codein phosphate hemihydrate	500 mg/30 mg	tablet	oral use
Norway	Actavis Group hf. - Reykjavikurvegur 76-78 - 220 Hafnarfjörður Iceland	Pinex Forte	Paracetamol/ Codein phosphate hemihydrate	500 mg/30 mg	suppository	rectal use
Norway	Weifa AS, Hausmannsgate 6, P.O.Box 9113 Grønland, NO-0133 Oslo, Norway	Paralgin Forte	Paracetamol/ Codein phosphate sesquihydrate	400mg/30 mg	suppository	rectal use
Norway	Weifa AS, Hausmannsgate 6, P.O.Box 9113 Grønland, NO-0133 Oslo, Norway	Paralgin Minor	Paracetamol/ Codein phosphate sesquihydrate	200mg/15 mg	suppository	rectal use
Norway	Weifa AS, Hausmannsgate 6, P.O.Box 9113 Grønland, NO-0133 Oslo, Norway	Paralgin Major	Paracetamol/ Codein phosphate sesquihydrate	800mg/60 mg	suppository	rectal use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Norway	Weifa AS, Hausmannsgate 6, P.O.Box 9113 Grønland, NO-0133 Oslo, Norway	Paralgin Forte	Paracetamol/ Codein phosphate sesquihydrate	400mg/30 mg	tablet	oral use
Poland	Bristol-Myers Squibb Polska Sp. z o.o. Al. Armii Ludowej 26 00-609 Warszawa Poland	Efferalgan Codeine	Paracetamolium + Codeini phosphas	500mg + 30mg	effervescent tablet	oral use
Poland	bene Arzneimittel GmbH Herterichstrasse 1 D-81479 Munchen Germany	Talvosilen Forte	Paracetamolium + Codeini phosphas hemihydricus	500mg + 30mg	capsule	oral use
Poland	bene Arzneimittel GmbH Herterichstrasse 1 D-81479 Munchen Germany	Talvosilen	Paracetamolium + Codeini phosphas hemihydricus	500mg + 20mg	tablet	oral use
Poland	Norpharma A/S Slotsmarken 15 DK-2970 Horsholm Denmark	DHC Continus	Dihydrocodeini tartras	60 mg	modified-release tablet	oral use
Poland	Norpharma A/S Slotsmarken 15 DK-2970 Horsholm Denmark	DHC Continus	Dihydrocodeini tartras	90 mg	modified-release tablet	oral use
Poland	Norpharma A/S Slotsmarken 15 DK-2970 Horsholm Denmark	DHC Continus	Dihydrocodeini tartras	120 mg	modified-release tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Poland	Bristol-Myers Squibb Polska Sp. z o.o. Al. Armii Ludowej 26 00-609 Warszawa Poland	Dafalgan codeine	Paracetamolum + Codeini phosphas	500mg + 30mg	film-coated tablet	oral use
Poland	Zentiva, k.s. U kabelovny 130 Praha 10 10237 Dolni Mecholupy Czech Republic	Ultracod	Paracetamolum + Codeini phosphas hemihydricus	500mg + 30mg	tablet	oral use
Poland	Vitabalans Oy Varastokatu 8 FIN-13500 Hameenlinna Finland	Paramax-Cod	Paracetamolum + Codeini phosphas hemihydricus	500mg + 30mg	tablet	oral use
Poland	Zakłady Farmaceutyczne POLPHARMA S.A. ul. Pelplińska 19 Starogard Gdański 83-200 Poland	Ascodan	Acidum acetylsalicylicum + Codeini phosphas	400mg + 8mg	tablet	oral use
Poland	Reckitt Benckiser (Poland) S.A. Okunin 1 Nowy Dwór Mazowiecki 05-100 Poland	Nurofen Plus	Ibuprofenum + Codeini phosphas	200mg + 12,8mg	film-coated tablet	oral use
Poland	OMEGA Pharma Poland Sp. z o.o. Niepodległości 18 02-653 Warsaw Poland	Solpadeine	Paracetamolum + Codeini phosphas + Coffeinum	500mg + 8mg + 30mg	capsule	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Poland	OMEGA Pharma Poland Sp. z o.o. Niepodleglosci 18 02-653 Warsaw Poland	Solpadeine	Paracetamolum + Coffeinum + Codeini phosphas	500mg + 30mg + 8mg	effervescent tablet	oral use
Poland	OMEGA Pharma Poland Sp. z o.o. Niepodleglosci 18 02-653 Warsaw Poland	Solpadeine	Paracetamolum + Codeini phosphas + Coffeinum	500mg + 8mg + 30mg	tablet	oral use
Portugal	Bayer Portugal, S.A. Rua Quinta do Pinheiro 5 2794-003 Carnaxide Portugal	Dolviran	Acetylsalicylic acid + Codeine phosphate hemihydrate + Caffeine	400mg + 9.6mg + 50mg	tablet	oral use
Portugal	Bayer Portugal, S.A. Rua Quinta do Pinheiro 5 2794-003 Carnaxide Portugal	Dolviran	Acetylsalicylic acid + Codeine phosphate hemihydrate + Caffeine	400mg + 9.6mg + 50mg	suppository	rectal use
Portugal	Johnson & Johnson, Lda. Estrada Consiglieri Pedroso, 69 A - Queluz de Baixo 2730-055 Barcarena Portugal	Migraleve	Paracetamol + Codeine phosphate + Buclizine hydrochloride	500mg + 8mg + 6.25mg	coated tablet	oral use
Romania	S.C. Fabiol S.A, B-dul Timișoara nr. 50, București, 61333 Romania	CODEINA FABIOL 15 mg	codeinum	15 mg	tablet	oral use
Romania	S.C. LaborMed Pharma S.A., B-dul Theodor Pallady nr. 44 B, sector 3, 032266 București, Romania	CODEINA FOSFAT LPH 15 mg	codeinum	15 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Romania	S.C. SINTOFARM S.A.Str. Ziduri între Vii nr.22, București, sector 3, 023324 Romania	FOSFAT DE CODEINA 15 mg	codeinum	15 mg	tablet	oral use
Romania	S.C. Farmacom S.A. Str. Zizinului Nr. 112, 2200 Brașov, 500407 Romania	FARMACOD	codeinum	15 mg	tablet	oral use
Romania	S.C. MAGISTRA C & C S.R.L.Bd-ul Aurel Vlaicu nr. 82 A, Constanța, Romania	CODEINA FOSFAT MCC 15 mg	codeinum	15 mg	tablet	oral use
Romania	S.C. Slavia Pharm S.R.L. Str. Știrbei Vodă Nr. 53-55, Sector 1, București, 10103 Romania	CODEINA FOSFAT	codeinum	15 mg	tablet	oral use
Romania	S.C. Bio EEL S.R.L.Str. Bega Nr. 4, Târgu-Mureș, 540390 Romania	CODEINA FOSFORICA	codeinum	15 mg	tablet	oral use
Romania	GEDEON RICHTER ROMÂNIA SA Str. Cuza Vodă nr. 99-105, Târgu-Mureș, Romania	FASCONAL	acid acetilsalicilic, paracetamol , fosfat de codeină hemihidrat , cafeină anhidră	200mg+200mg+10 mg+25mg	tablet	oral use
Romania	S.C. Bio EEL S.R.L.Str. Bega Nr. 4, Târgu-Mureș, 540390 Romania	ASPACO	acid acetilsalicilic, paracetamol , fosfat de codeină hemihidrat	300mg + 250mg + 12mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Romania	HIPOCRATE 2000 S.R.L. Str. Prahova, Nr. 6A, Sector 1, București 012423 Romania	SOLPADEINE 500 mg/8 mg/30 mg comprimate efervescente	paracetamol, fosfat de codeină hemihidrat, cafeină anhidră	500 mg+8 mg+30 mg	effervescent tablet	oral use
Romania	HIPOCRATE 2000 S.R.L. Str. Prahova, Nr. 6A, Sector 1, București 012423 România	SOLPADEINE COMPRIMATE	paracetamol, fosfat de codeină hemihidrat, cafeină anhidră	500 mg+8 mg+30 mg	tablet	oral use
Romania	S.C. TERAPIA S.A Str. Fabricii Nr.124, Cluj-Napoca, Județul Cluj, 400632 Romania	CODAMIN P	paracetamol, cafeină anhidră, fosfat de codeină hemihidrat	400mg+23mg+15mg	tablet	oral use
Romania	ALKALOID - INT d.o.o Šlandrova ulica 4, 1231 Ljubljana - Črnuče, Slovenia	CAFFETIN	paracetamol, propifenazonă, cafeină, fosfat de codeină sesquihidrat	250mg+210mg+50mg+10 mg	tablet	oral use
Romania	Zentiva, k.s.U kabelovny 130, Dolní Měcholupy 102 37, Praga 10, Czech Republic	ULTRACOD 500 mg/30 mg	paracetamol + codeinum	500mg/30mg	tablet	oral use
Romania	RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED 103-105 Bath Road, Slough, Berkshire SL1 3UH, United Kingdom	NUROFEN PLUS	ibuprofen, fosfat de codeină hemihidrat	200mg + 12,8 mg	film-coated tablet	oral use
Slovak Republic	Zentiva a.s. Nitrianska 100, Hlohovec 920 27 Slovak Republic	Alnagon Neo (Zentiva)	acetylsalicylic acid + codeine + caffeine	380 mg + 20 mg + 80 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Slovak Republic	Zentiva a.s. Nitrianska 100, Hlohovec 920 27 Slovak Republic	Codein-SLOVAKOFARMA 15 mg	codeine	15 mg	tablet	oral use
Slovak Republic	Zentiva a.s. Nitrianska 100, Hlohovec 920 27 Slovak Republic	Codein-SLOVAKOFARMA 30 mg	codeine	15 mg	tablet	oral use
Slovak Republic	Zentiva k.s. U kabelovny 130, Praha 102 37 Czech Republic	Korylan	codeine + paracetamol	21,17 mg +325 mg	tablet	oral use
Slovak Republic	GlaxoSmithKline Consumer Healthcare, GlaxoSmithKline Export Ltd. 980 Great West Road, TW8 9GS Brentford United Kingdom	Panadol Ultra, Panadol Ultra Rapide	codeine + paracetamol + caffeine	8 mg+500 mg +30 mg	capsule, tablet, effervescent tablet	oral use
Slovak Republic	Vitabalans Oy Varastokatu 8, Hämeenlinna FI-13500 Finland	Paramax-Cod (Vitabalans)	codeine + paracetamol	30 mg +500 mg	tablet	oral use
Slovak Republic	Zentiva k.s. U kabelovny 130, Praha 102 37 Czech Republic	Spasmopan	codeine + paracetamol + fenpiverine + pitofenon	19,2 mg+500 mg+0,1 mg +10 mg	suppository	rectal use
Slovenia	Alkaloid-Int. d.o.o. Šlandrova 4, 1231 Ljubljana- Črnuče Slovenia	Caffetin tablete	codeine, paracetamol, propyphenazone, caffeine	10 mg, 250 mg, 210 mg, 50 mg	tablet	oral use
Slovenia	Pliva Ljubljana d.o.o., Pot k sejmišču 35, 1000 Ljubljana, Slovenia	Plivadon tablete	codeine, paracetamol, propyphenazone, caffeine	10 mg, 210 mg, 250 mg, 25 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Spain	TEVA PHARMA, S.L.U. C/ Anabel Segura, 11 Edificio Albatros B, 1ª planta 28108 Alcobendas (Madrid) Spain	CODEISAN COMPRIMIDOS	Codeine phosphate hemihydrate	28,7 mg	tablet	oral use
Spain	TEVA PHARMA, S.L.U. C/ Anabel Segura, 11 Edificio Albatros B, 1ª planta 28108 Alcobendas (Madrid) Spain	CODEISAN JARABE	Codeine phosphate hemihydrate	6,33 mg/ 5 ml	oral solution	oral use
Spain	VIFOR PHARMA ESPAÑA, S.L. Avda. Camí Real, 51-57 08184 Palau-Solità i Plegamans (Barcelona) Spain	DOLMEN	Acetylsalicylic acid, codeine phosphate hemihydrate and ascorbic acid	500 mg, 10 mg and 250 mg	effervescent tablet	oral use
Spain	LABORATORIOS ASOCIADOS NUPEL, S.L. Rua Carpeinteiros, 25 Polígono Industrial Ceao 27003 Lugo Spain	DOLODENS GRAGEAS	Codeine phosphate, hydroxicine dichlorhydrate and propifenazone	10 mg, 15 mg and 100 mg	coated tablet	oral use
Spain	TEOFARMA, S.R.L. Via F. Lli Cervi, 8 27010 Valle Sambrene (Pavia) Italy	CALMOPLEX 200 mg/ 10 mg/ 10 mg comprimidos recubiertos	Codeine phosphate, hydroxicine dichlorhydrate and propifenazone	10 mg, 10 mg and 200 mg	coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Spain	FAES FARMA, S.A. Máximo Aguirre, 14 48940 Lamiaco-Lejona (Vizcaya) Spain	ANALGILASA COMPRIMIDOS RECUBIERTOS	Paracetamol and codeine phosphate and caffeine	500 mg, 10 mg and 30 mg	film-coated tablet	oral use
Spain	FAES FARMA, S.A. Máximo Aguirre, 14 48940 Lamiaco-Lejona (Vizcaya) Spain	ANALGIPLUS 500 mg/ 30 mg comprimidos recubiertos con película	Paracetamol and codeine phosphate hemihydrate	500 mg and 30 mg	film-coated tablet	oral use
Spain	KERN PHARMA, S.L. Venus, 72 Polígono Industrial Colon II 08228 Tarrasa (Barcelona) Spain	DOLOMEDIL COMPRIMIDOS	Paracetamol and codeine phosphate	500 mg and 10 mg	tablet	oral use
Spain	KERN PHARMA, S.L. Venus, 72 Polígono Industrial Colon II 08228 Tarrasa (Barcelona) Spain	DOLVIRÁN COMPRIMIDOS	Acetylsalicylic acid, codeine phosphate hemihydrate and caffeine	400 mg, 9.6 mg and 50 mg	tablet	oral use
Spain	KERN PHARMA, S.L. Venus, 72 Polígono Industrial Colon II 08228 Tarrasa (Barcelona) Spain	DOLVIRÁN SUPOSITARIOS	Acetylsalicylic acid, Codeine phosphate hemihydrate and caffeine	400 mg, 9.6 mg and 50 mg	suppository	rectal use
Spain	ALMIRALL, S.A. Ronda General Mitre, 151 08022 Barcelona Spain	ALGIDOL SOBRES	Paracetamol and codeine phosphate and ascorbic acid	650 mg, 10 mg and 500 mg	powder for oral suspension	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Spain	FERRER INTERNACIONAL, S.A. Gran Vía Carlos III, 94 08028 Barcelona Spain	DOLOCATIL CODEÍNA 325 mg/ 15 mg comprimidos	Paracetamol, codeine phosphate hemihydrate	325 mg and 15 mg	tablet	oral use
Spain	FERRER INTERNACIONAL, S.A. Gran Vía Carlos III, 94 08028 Barcelona Spain	DOLOCATIL CODEÍNA 650 mg/ 30 mg comprimidos	Paracetamol and codeine phosphate hemihydrate	650 mg and 30 mg	tablet	oral use
Spain	FERRER INTERNACIONAL, S.A. Gran Vía Carlos III, 94 08028 Barcelona Spain	DOLOCATIL CODEÍNA 500 mg/ 15 mg comprimidos	Paracetamol and codeine phosphate	500 mg and 15 mg	tablet	oral use
Spain	BRISTOL MYERS SQUIBB, S.A. Quintanavides, 15 28050 Madrid Spain	COD-EFFERALGAN 500 mg/ 30 mg comprimidos efervescentes	Paracetamol and codeine phosphate hemihydrate	500 mg and 30 mg	effervescent tablet	oral use
Spain	LABORATORIOS ERN, S.A. Pedro IV, 499 08022 Barcelona Spain	PARACETAMOL CODEÍNA LEVEL SOLUCIÓN ORAL	Paracetamol and codeine phosphate	120 mg and 12 mg / 5 ml	oral solution	oral use
Spain	LABORATORIOS ERN, S.A. Pedro IV, 499 08022 Barcelona Spain	TALGO CODEÍNA COMPRIMIDOS	Paracetamol and codeine phosphate	300 mg and 30 mg	tablet	oral use
Spain	ITALFARMACO, S.A. San Rafael, 3 28108 Alcobendas (Madrid) Spain	COXUMADOL	Paracetamol and codeine phosphate hemihydrate	500 mg and 30 mg	effervescent granules	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Spain	FARMASIERRA LABORATORIOS, S.L. Ctra. Irún, Km. 26.200 28700 San Sebastián de los Reyes (Madrid) Spain	ASTEFOR 400 mg/30 mg granulado para suspensión oral	Ibuprofen and codeine phosphate hemihydrate	400 mg and 30 mg	granules for oral suspension	oral use
Spain	FARMASIERRA LABORATORIOS, S.L. Ctra. Irún, Km. 26.200 28700 San Sebastián de los Reyes (Madrid) Spain	ASTEFOR 400 mg/30 mg comprimidos recubiertos con película	Ibuprofen and codeine phosphate hemihydrate	400 mg and 30 mg	film-coated tablet	oral use
Spain	ABBOTT LABORATORIES, S.A. Avda. de Burgos, 91 28050 Madrid Spain	NEOBRUFEN CON CODEÍNA 400 mg/ 30 mg comprimidos recubiertos con película	Ibuprofen and codeine phosphate hemihydrate	400 mg and 30 mg	film-coated tablet	oral use
Spain	CANTABRIA PHARMA, S.L. C/ Ribera del Loira, 46 Edificio 2 28042 Madrid Spain	NIDOL 400 mg/ 30 mg comprimidos recubiertos con película	Ibuprofen and codeine phosphate hemihydrate	400 mg and 30 mg	film-coated tablet	oral use
Spain	FARMALIDER, S.A. Aragoneses, 15 28108 Madrid Spain	HYTRIN 200 mg/ ml + 10 mg/ ml solución oral	Ibuprofen and codeine phosphate hemihydrate	200 mg and 10 mg /1 ml	oral solution	oral use
Spain	FARMALIDER, S.A. Aragoneses, 15 28108 Madrid Spain	IBUCOD 200 mg/ ml + 10 mg/ ml solución oral	Ibuprofen and codeine phosphate hemihydrate	200 mg and 10 mg /1 ml	oral solution	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Spain	KERN PHARMA, S.L. Venus, 72 Polígono Industrial Colon II 08228 Tarrasa (Barcelona) Spain	PARACETAMOL/CODEÍNA KERN PHARMA 500 mg/ 30 mg comprimidos EFG	Paracetamol and codeine phosphate hemihydrate	500 mg and 30 mg	tablet	oral use
Spain	KERN PHARMA, S.L. Venus, 72 Polígono Industrial Colon II 08228 Tarrasa (Barcelona) Spain	PARACETAMOL/CODEÍNA PHARMAKERN 500 mg/ 30 mg comprimidos EFG	Paracetamol and codeine phosphate hemihydrate	500 mg and 30 mg	tablet	oral use
Spain	NOVARTIS CONSUMER HEALTH, S.A. Gran Vía de les Corts Catalanes, 764 08013 Barcelona Spain	TERMALGIN CODEINA 650 mg/30 mg supositorios	Paracetamol and anhydrous codeine phosphate	650 mg and 28,09 mg	suppository	rectal use
Spain	NOVARTIS CONSUMER HEALTH, S.A. Gran Vía de les Corts Catalanes, 764 08013 Barcelona Spain	TERMALGIN CODEINA 300 mg/15 mg cápsulas	Paracetamol and anhydrous codeine phosphate	300 mg and 14,05 mg	capsule, hard	oral use
Spain	LABORATORIOS ALTER, S.A. Mateo Inurria, 30 28036 Madrid Spain	FLUDETEN comprimidos efervescentes	Paracetamol and codeine phosphate	500 mg and 30 mg	effervescent tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Spain	LABORATORIOS LLORENS, S.A. Ciudad de Balaguer, 7-11 08022 Barcelona Spain	MIGRALEVE comprimidos	Paracetamol, Buclizine chlorhydrate, codeine phosphate and docusate sodium	500 mg, 6,25 mg, 8 mg and 10 mg	tablet	oral use
Sweden	BioPhausia AB Blasieholmsgatan 2 111 48 Stockholm Sweden	Citodon minor	Kodein/Paracetamol	350mg/15mg	suppository	rectal use
Sweden	BioPhausia AB Blasieholmsgatan 2 111 48 Stockholm Sweden	Citodon forte	Kodein/Paracetamol	1000mg/60 mg	suppository	rectal use
Sweden	BioPhausia AB Blasieholmsgatan 2 111 48 Stockholm Sweden	Citodon	Kodein/Paracetamol	500 mg/30 mg	tablet	oral use
Sweden	BioPhausia AB Blasieholmsgatan 2 111 48 Stockholm Sweden	Citodon	Kodein/Paracetamol	500 mg/30 mg	suppository	rectal use
Sweden	BioPhausia AB Blasieholmsgatan 2 111 48 Stockholm Sweden	Citodon	Kodein/Paracetamol	500 mg/30 mg	effervescent tablet	oral use
Sweden	Meda AB Box 906 170 09 Solna Sweden	Treo® comp	codeine phosphate hemihydrate/caffeine/ acetylsalicylic acid	500mg/50mg/30mg	effervescent tablet	oral use
Sweden	Meda AB Box 906 170 09 Solna Sweden	Codalvonil	codeine phosphate hemihydrate/ paracetamol	500 mg/30 mg	effervescent tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Sweden	sanofi-aventis AB Box: 14142 167 14 Bromma Sweden	Panocod®	codeine phosphate hemihydrate/ paracetamol	500 mg/30 mg	tablet	oral use
Sweden	sanofi-aventis AB Box: 14142 167 14 Bromma Sweden	Panocod®	codeine phosphate hemihydrate/ paracetamol	500 mg/30 mg	effervescent tablet	oral use
Sweden	Recip AB Box: 906 170 09 Solna Sweden	Kodein Recip	codeine phosphate hemihydrate	25mg	tablet	oral use
Sweden	Mundipharma AB, Mölnåsvägen 30 412 63 Göteborg Sweden	Ardinex®	ibuprofen/codeine phosphate hemihydrate	200 mg/30 mg	tablet	oral use
Sweden	Evolan Pharma AB Box: 120 182 12 Danderyd Sweden	Paracetamol/Kodein Evolan	codeine phosphate hemihydrate/ paracetamol	500 mg/30 mg	effervescent tablet	oral use
Sweden	Evolan Pharma AB Box: 120 182 12 Danderyd Sweden	Paracetamol/Kodein Evolan	codeine phosphate hemihydrate/ paracetamol	500 mg/30 mg	tablet	oral use
Sweden	Meda AB Box 906 170 09 Solna Sweden	Spasmofen	codeine hydrochloride dihydrate, papaverine hydrochloride, morphine hydrochloride, hyoscine methonitrate, noscapine hydrochloride	0,4 mg, 20 mg, 6,6 mg, 0,15 mg, 3 mg (in each ml)	solution for injection	parenteral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
Sweden	Meda AB Box 906 170 09 Solna Sweden	Spasmofen	codeine hydrochloride dihydrate, papaverine hydrochloride, morphine hydrochloride, hyoscine methonitrate, noscapine hydrochloride	0,8mg, 40 mg, 13 mg, 0,5 mg, 6 mg	suppository	rectal use
The Netherlands	ratiopharm Nederland B.V. Florapark 4 2012 HK Haarlem The Netherlands	Paracetamol/Codeinefosfaat ratiopharm 500 mg/20 mg, tabletten	Paracetamol Codeine	500 mg 20 mg	tablet	oral use
The Netherlands	Pharmachemie B.V. Swensweg 5 2031 GA Haarlem The Netherlands	Codeine HCl 10 PCH, tabletten 10 mg	Codeine	10 mg	tablet	oral use
The Netherlands	Pharmachemie B.V. Swensweg 5 2031 GA Haarlem The Netherlands	Codeine HCl 20 PCH, tabletten 20 mg	Codeine	20 mg	tablet	oral use
The Netherlands	ratiopharm Nederland B.V. Florapark 4 2012 HK Haarlem The Netherlands	Codeinefosfaat ratiopharm 10 mg, tabletten	Codeine	10 mg	tablet	oral use
The Netherlands	ratiopharm Nederland B.V. Florapark 4 2012 HK Haarlem The Netherlands	Codeinefosfaat ratiopharm 20 mg, tabletten	Codeine	20 mg	tablet	oral use
The Netherlands	Pharmachemie B.V. Swensweg 5 2031 GA Haarlem The Netherlands	Codeinefosfaat 10 PCH, tabletten 10 mg	Codeine	10 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
The Netherlands	Pharmachemie B.V. Swensweg 5 2031 GA Haarlem The Netherlands	Codeinefostaat 15 PCH, tabletten 15 mg	Codeine	15 mg	tablet	oral use
The Netherlands	Pharmachemie B.V. Swensweg 5 2031 GA Haarlem The Netherlands	Codeinefostaat 20 PCH, tabletten 20 mg	Codeine	20 mg	tablet	oral use
The Netherlands	Pharmachemie B.V. Swensweg 5 2031 GA Haarlem The Netherlands	Paracetamol/Codeinefosfaat 500/20 PCH, tabletten 500 mg/20 mg	Paracetamol Codeine	500 mg 20 mg	tablet	oral use
The Netherlands	Pharmachemie B.V. Swensweg 5 2031 GA Haarlem The Netherlands	Paracetamol/Codeinefosfaat 500/50 PCH, tabletten 500 mg/50 mg	Paracetamol Codeine	500 mg 50 mg	tablet	oral use
The Netherlands	Apotex Europe B.V. Darwinweg 20 2333 CR Leiden The Netherlands	Paracetamol/codeinefosfaat Apotex 500/10 mg, tabletten	Paracetamol Codeine	500 mg 10 mg	tablet	oral use
The Netherlands	Apotex Europe B.V. Darwinweg 20 2333 CR Leiden The Netherlands	Paracetamol/codeinefosfaat Apotex 500/20 mg, tabletten	Paracetamol Codeine	500 mg 20 mg	tablet	oral use
The Netherlands	Pharmachemie B.V. Swensweg 5 2031 GA Haarlem The Netherlands	Paracetamol/Codeinefosfaat 500/10 PCH, tabletten 500 mg/10 mg	Paracetamol Codeine	500 mg 10 mg	tablet	oral use
The Netherlands	ratiopharm Nederland B.V. Florapark 4 2012 HK Haarlem The Netherlands	Paracetamol/Codeinefosfaat ratiopharm 500 mg/10 mg, tabletten	Paracetamol Codeine	500 mg 10 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
The Netherlands	Pharmachemie B.V. Swensweg 5 2031 GA Haarlem The Netherlands	A.C. Cod., suppositoria	Acetylsalicylic acid Codeine Caffeine	400 mg 9.6 mg 50 mg	suppository	rectal use
United Kingdom	Bayer plc, Bayer House, Strawberry Hill, Newbury, Berkshire RG14 1JA, United Kingdom	Co-Codamol Disp	paracetamol + codeine	500mg + 8mg	tablet for oral solution	oral use
United Kingdom	Bayer plc, Bayer House, Strawberry Hill, Newbury, Berkshire RG14 1JA, United Kingdom	Paracodol Capsules	paracetamol + codeine	500mg + 8mg	capsule	oral use
United Kingdom	Bayer plc, Bayer House, Strawberry Hill, Newbury, Berkshire RG14 1JA, United Kingdom	Paracodol Tablets	paracetamol + codeine	500mg + 8mg	tablet for oral solution	Oral use
United Kingdom	Bayer plc, Bayer House, Strawberry Hill, Newbury, Berkshire RG14 1JA, United Kingdom	Bayer Co-Codamol 8/500mg capsules	paracetamol + codeine	500mg + 8mg	capsule, hard	Oral use
United Kingdom	The Boots Company Plc, 1 Thane Road West, NG2 3AA, Nottingham, United Kingdom	Boots Aspirin and Codeine Tablets	aspirin + codeine phosphate	400mg + 8mg	tablet	Oral use
United Kingdom	The Boots Company Plc, 1 Thane Road West, NG2 3AA, Nottingham, United Kingdom	Paracetamol and Codeine Caplets	paracetamol + codeine	500mg + 8mg	tablet	Oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom	The Boots Company Plc, 1 Thane Road West, NG2 3AA, Nottingham, United Kingdom	Boots Pain Relief Plus Capsules	paracetamol + codeine	500mg + 8mg	capsule	Oral use
United Kingdom	The Boots Company Plc, 1 Thane Road West, NG2 3AA, Nottingham, United Kingdom	Boots Paracetamol and Codeine Extra Capsules	paracetamol + codeine + caffeine	500mg + 8mg + 30mg	capsule, hard	Oral use
United Kingdom	The Boots Company Plc, 1 Thane Road West, NG2 3AA, Nottingham, United Kingdom	Boots Ibuprofen and Codeine Tablets	ibuprofen + codeine	200mg + 12.8mg	film-coated tablet	Oral use
United Kingdom	UCB Pharma Limited, 208 Bath Road, Slough, Berkshire SL1 3WE, United Kingdom	Tylox Tablets	paracetamol + codeine	500mg + 8mg	coated tablet	oral use
United Kingdom	UCB Pharma Limited, 208 Bath Road, Slough, Berkshire SL1 3WE, United Kingdom	Medocodene 30/500 Capsules	paracetamol + codeine	500mg + 30mg	capsule	oral use
United Kingdom	UCB Pharma Limited, 208 Bath Road, Slough, Berkshire SL1 3WE, United Kingdom	Tylox 30/500 Effervescent	paracetamol + codeine	500mg + 30mg	effervescent tablet	oral use
United Kingdom	Reckitt Benkiser Healthcare (UK) Limited, Wellcroft House, Wellcroft Road, Slough, Berkshire SL1 4AQ, United Kingdom	Codis 500 Tablets	paracetamol + codeine	500mg + 8mg	tablet for oral solution	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom	Reckitt Benckiser Healthcare (UK) Limited, Wellcroft House, Wellcroft Road, Slough, Berkshire SL1 4AQ, United Kingdom	Nurofen Plus	ibuprofen + codeine	200mg + 12.8mg	coated tablet	oral use
United Kingdom	Omega Pharma Limited 32 Vauxhall Bridge Road London SW1V 2SA United Kingdom	Solpadeine Plus Capsules	paracetamol + codeine + caffeine	500mg + 8mg + 30mg	capsule	oral use
United Kingdom	Omega Pharma Limited 32 Vauxhall Bridge Road London SW1V 2SA United Kingdom	Solpadeine Max	paracetamol + codeine	500mg + 12.8mg	tablet	oral use
United Kingdom	Omega Pharma Limited 32 Vauxhall Bridge Road London SW1V 2SA United Kingdom	Solpadeine Max Soluble Tablets	paracetamol + codeine + caffeine	500mg + 12.8mg + 30mg	effervescent tablet	oral use
United Kingdom	Omega Pharma Limited 32 Vauxhall Bridge Road London SW1V 2SA United Kingdom	Solpadeine Plus Soluble Tablets	paracetamol + codeine + caffeine	500mg + 8mg + 30mg	tablet for oral solution	oral use
United Kingdom	Omega Pharma Limited 32 Vauxhall Bridge Road London SW1V 2SA United Kingdom	Solpadeine Plus Tablets	paracetamol + codeine + caffeine	500mg + 8mg + 30mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom	Omega Pharma Limited 32 Vauxhall Bridge Road London SW1V 2SA United Kingdom	Solpaflex Tablets	ibuprofen + codeine	200mg + 12.8mg	film-coated tablet	oral use
United Kingdom	Omega Pharma Limited 32 Vauxhall Bridge Road London SW1V 2SA United Kingdom	Solpadeine Max Tablets	paracetamol + codeine	500mg + 12.8mg	film-coated tablet	oral use
United Kingdom	Actavis UK Limited Whiddon Valley, Barnstaple, Devon, EX32 8NS United Kingdom	Dispersible Co-Codaprin Tablets BP	aspirin + codeine phosphate	400mg + 8mg	tablet for oral solution	oral use
United Kingdom	Actavis UK Limited Whiddon Valley, Barnstaple, Devon, EX32 8NS United Kingdom	Cox Co-Codamol Tablets	paracetamol + codeine	500mg + 8mg	tablet	oral use
United Kingdom	Actavis UK Limited Whiddon Valley, Barnstaple, Devon, EX32 8NS United Kingdom	Cox Codeine Phosphate Tablets BP 15mg	codeine phosphate	15mg	tablet	oral use
United Kingdom	Actavis UK Limited Whiddon Valley, Barnstaple, Devon, EX32 8NS United Kingdom	Codeine Phosphate Tablets BP 30mg	codeine phosphate	30mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom	Actavis UK Limited Whiddon Valley, Barnstaple, Devon, EX32 8NS United Kingdom	Codeine Phosphate Tablets BP 60mg	codeine phosphate	60mg	tablet	oral use
United Kingdom	Teva UK Limited, Brampton Road, Hampden Park, Eastbourne, East Sussex BN22 9AG, United Kingdom	Teva UK Co-Codamol Tablets 8/500	paracetamol + codeine	500mg + 8mg	tablet	oral use
United Kingdom	Teva UK Limited, Brampton Road, Hampden Park, Eastbourne, East Sussex BN22 9AG, United Kingdom	Codeine Phosphate Tablets BP 15mg	codeine phosphate	15mg	tablet	oral use
United Kingdom	Teva UK Limited, Brampton Road, Hampden Park, Eastbourne, East Sussex BN22 9AG, United Kingdom	Codeine Phosphate Tablets BP 30mg	codeine phosphate	30mg	tablet	oral use
United Kingdom	Teva UK Limited, Brampton Road, Hampden Park, Eastbourne, East Sussex BN22 9AG, United Kingdom	Codeine Phosphate Tablets BP 60mg	codeine phosphate	60mg	tablet	oral use
United Kingdom	Macarthy's Laboratories Limited, Bampton Road, Harold Hill, Romford, Essex RM3 8UG, United Kingdom	Macarthy's Codeine Phosphate Injection BP 60mg/ml	codeine phosphate	6.1% w/v	Solution for Injection	intramuscular

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom	Chefaro UK Limited, 3 Percy Road, Huntingdon PE29 6SZ, United Kingdom	Veganin	paracetamol + codeine + caffeine	500mg + 8mg + 30mg	film-coated tablet	oral use
United Kingdom	M & A Pharmachem Limited, Allenby Laboratories, Wigan Road, Westhoughton, Bolton, Lancashire BL5 2AL, United Kingdom	Pharmachem Co-Codamol Tablets 8/500	paracetamol + codeine	500mg + 8mg	tablet	oral use
United Kingdom	M & A Pharmachem Limited, Allenby Laboratories, Wigan Road, Westhoughton, Bolton, Lancashire BL5 2AL, United Kingdom	M&A Pharmachem Co-Codamol Tablets 30/500	paracetamol + codeine	500mg + 30mg	tablet	oral use
United Kingdom	M & A Pharmachem Limited, Allenby Laboratories, Wigan Road, Westhoughton, Bolton, Lancashire BL5 2AL, United Kingdom	M&A Pharmachem Co-Codamol Tablets 60/500	paracetamol + codeine	500mg + 60mg	tablet	oral use
United Kingdom	Sandoz Limited, Frimley Business Park, Frimley, Camberley, Surrey GU16 7SR, United Kingdom	Codeine Phosphate Tablets BP 15mg	codeine phosphate	15mg	tablet	oral use
United Kingdom	Sandoz Limited, Frimley Business Park, Frimley, Camberley, Surrey GU16 7SR, United Kingdom	Codeine Phosphate Tablets BP 30mg	codeine phosphate	30mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom	Sandoz Limited, Frimley Business Park, Frimley, Camberley, Surrey GU16 7SR, United Kingdom	Codeine Phosphate Tablets BP 60mg	codeine phosphate	60mg	tablet	oral use
United Kingdom	Sandoz Limited, Frimley Business Park, Frimley, Camberley, Surrey GU16 7SR, United Kingdom	Propain Plus Tablets	paracetamol + doxylamine succinate + caffeine + codeine	450mg + 5mg + 30mg + 10 mg	tablet	oral use
United Kingdom	Sandoz Limited, Frimley Business Park, Frimley, Camberley, Surrey GU16 7SR, United Kingdom	Propain tablets	paracetamol + diphenhydramine hydrochloride + caffeine + codeine	400mg + 5mg + 50mg + 10mg	tablet	oral use
United Kingdom	Sandoz Limited, Frimley Business Park, Frimley, Camberley, Surrey GU16 7SR, United Kingdom	Sandoz Co-Codamol Tablets 30/500mg	paracetamol + codeine	500mg + 30mg	tablet	oral use
United Kingdom	Aventis Pharma Limited, One Onslow Street, Guilford, Surrey GU1 4SY United Kingdom	Aventis Pharam Co-codamol Capsules 30mg/500mg	Codeine phosphate + paracetamol	30mg + 500 mg	capsule, hard	oral use
United Kingdom	Aventis Pharma Limited, One Onslow Street, Guilford, Surrey GU1 4SY United Kingdom	Solpadol Tablets	Codeine phosphate + paracetamol	30mg + 500 mg	effervescent tablet	Oral use
United Kingdom	Aventis Pharma Limited, One Onslow Street, Guilford, Surrey GU1 4SY United Kingdom	Solpadol Tablets	Codeine phosphate + paracetamol	30mg + 500 mg	tablet	Oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom	Waymade Plc, Sovereign House, Miles Gray Road, Basildon, Essex SS14 3FR United Kingdom	Waymade codeine phosphate tablets 15mg	Codeine phosphate	15mg	tablet	Oral use
United Kingdom	Waymade Plc, Sovereign House, Miles Gray Road, Basildon, Essex SS14 3FR United Kingdom	Codeine phosphate 30mg tablets	Codeine phosphate	30mg	tablet	Oral use
United Kingdom	Waymade Plc, Sovereign House, Miles Gray Road, Basildon, Essex SS14 3FR United Kingdom	Codeine phosphate 60mg tablets	Codeine phosphate	60mg	tablet	Oral use
United Kingdom	Ranbaxy Ireland Limited, Spafield, Cork Road, Cashel, Co. Tipperary Ireland	Codeine phosphate tablets BP 15mg	Codeine phosphate	15mg	tablet	Oral use
United Kingdom	Ranbaxy Ireland Limited, Spafield, Cork Road, Cashel, Co. Tipperary Ireland	Codeine phosphate tablets BP 30mg	Codeine phosphate	30mg	tablet	Oral use
United Kingdom	Ranbaxy Ireland Limited, Spafield, Cork Road, Cashel, Co. Tipperary Ireland	Codeine phosphate Tablets 60mg BP	Codeine phosphate	60mg	tablet	Oral use
United Kingdom	Aspar Pharmaceuticals Limited, 29-30 Capitol Way, Colindale, London NW9 0EQ United Kingdom	Aspar Pharms Co-codamol Tablets 8mg/500mg	Codeine phosphate + paracetamol	8mg + 500mg	tablet	Oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom	Aspar Pharmaceuticals Limited, 29-30 Capitol Way, Colindale, London NW9 0EQ United Kingdom	Aspar Pharms Co-codamol Tablets BP 8/500mg	Codeine phosphate + paracetamol	8mg + 500mg	tablet	Oral use
United Kingdom	Tillomed Laboratories Limited, 3 Howard Road, Eaton Socon, St Neots, Cambridgeshire PE19 8ET United Kingdom	Tillomed Labs Co-codamol Tablets 8mg/500mg	Codeine phosphate + paracetamol	8mg + 500mg	tablet	Oral use
United Kingdom	Wrafton Laboratories Limited, Exeter Road, Wrafton, Braunton, Devon EX33 2DL United Kingdom	Teva Dual Action Pain Relief Capsules	Codeine phosphate hemihydrate + caffeine + paracetamol	8mg + 30mg + 500 mg	capsule	Oral use
United Kingdom	Wrafton Laboratories Limited, Exeter Road, Wrafton, Braunton, Devon EX33 2DL United Kingdom	Wrafton Labs Co-codamol Plus Caffeine Tablets	Codeine phosphate hemihydrate + caffeine + paracetamol	8mg + 30mg + 500 mg	tablet	Oral use
United Kingdom	Mercury Pharmaceuticals Limited, No. 1 Croydon, 12-16 Addiscombe Road, Croydon, Surrey CR0 0XT United Kingdom	Mercury Pharms Co-codamol Capsules 30mg/500mg	Codeine phosphate + paracetamol	30mg + 500 mg	capsule	Oral use
United Kingdom	Mercury Pharmaceuticals Limited, No. 1 Croydon, 12-16 Addiscombe Road, Croydon, Surrey CR0 0XT United Kingdom	Mercury Pharms Co-codamol Tablets 30mg/500mg	Codeine phosphate + paracetamol	30mg + 500 mg	tablet	Oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom	Mercury Pharmaceuticals Limited, No. 1 Croydon, 12-16 Addiscombe Road, Croydon, Surrey CR0 0XT United Kingdom	Mercury Pharms Co-codamol Tablets 15mg/500mg	Codeine phosphate + paracetamol	15mg + 500mg	Coated tablet	Oral use
United Kingdom	Mercury Pharmaceuticals Limited, No. 1 Croydon, 12-16 Addiscombe Road, Croydon, Surrey CR0 0XT United Kingdom	Codipar effervescent tablets 15mg/500mg	Codeine phosphate hemihydrate + paracetamol	15mg + 500mg	effervescent tablet	Oral use
United Kingdom	Mercury Pharmaceuticals Limited, No. 1 Croydon, 12-16 Addiscombe Road, Croydon, Surrey CR0 0XT United Kingdom	Mercury Pharms Co-codamola effervescent tablets 30mg/500mg	Codeine phosphate hemihydrate + paracetamol	30mg + 500 mg	effervescent tablet	Oral use
United Kingdom	Mercury Pharmaceuticals Limited, No. 1 Croydon, 12-16 Addiscombe Road, Croydon, Surrey CR0 0XT United Kingdom	Codipar Capsules 15mg/500mg	Codeine phosphate + paracetamol	15mg + 500mg	capsule, hard	Oral use
United Kingdom	South Devon Healthcare NHS Foundation Trust, Torbay PMU, Long Road, Paignton, Devon TQ4 7TW United Kingdom	Codeine phosphate injection 60mg in 1ml	Codeine phosphate	60mg/ml	Solution for injection	Intramuscular

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom	McNeil Products Limited, Foundation Park, Roxborough Way, Maidenhead, Berkshire SL6 3UG United Kingdom	Warner-Lambert CH Migravele Pink Tablets	Codeine phosphate + paracetamol + buclizine hydrochloride	8mg + 520mg + 6.25mg	Coated tablet	Oral use
United Kingdom	McNeil Products Limited, Foundation Park, Roxborough Way, Maidenhead, Berkshire SL6 3UG United Kingdom	Warner-Lambert CH Migravele Yellow Tablets	Codeine phosphate + paracetamol	8mg + 520mg	Coated tablet	Oral use
United Kingdom	McNeil Products Limited, Foundation Park, Roxborough Way, Maidenhead, Berkshire SL6 3UG United Kingdom	Warner-Lambert CH Migravele Tablets	Codeine phosphate + paracetamol + buclizine hydrochloride	8mg + 520mg + 6.25mg	Coated tablet	Oral use
United Kingdom	Manx Pharma Limited, Taylor Group House, Wedgnock Lane, Warwick CV34 5YA United Kingdom	Manx Pharma Co-codamol 30 mg/500 mg effervescent tablets	Codeine phosphate hemihydrate + paracetamol	30mg + 500 mg	effervescent tablet	Oral use
United Kingdom	Ayrton Saunders Limited, 9 Arkwright Road, Astmoor Industrial Estate, Runcorn, Cheshire WA7 1NU United Kingdom	Soluble Cupanol-Co Lemon Flavour	Codeine phosphate + paracetamol	8mg + 500mg	effervescent tablet	Oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom	Ayrton Saunders Limited, 9 Arkwright Road, Astmoor Industrial Estate, Runcorn, Cheshire WA7 1NU United Kingdom	Co-codaprin Tablets	Codeine phosphate + aspirin	8mg + 400mg	tablet	Oral use
United Kingdom	Winthrop Pharmaceuticals UK Limited, One Onslow Street, Guildford, Surrey GU1 4YS United Kingdom	Winthrop Pharms UK Co-codamol 30mg/500mg	Codeine phosphate hemihydrate + paracetamol	30mg + 500mg	tablet	Oral use
United Kingdom	Winthrop Pharmaceuticals UK Limited, One Onslow Street, Guildford, Surrey GU1 4YS United Kingdom	Sterwin Meds Co-codamol 30/500 effervescent tablets 30mg/500mg	Codeine phosphate hemihydrate + paracetamol	30mg + 500mg	effervescent tablet	oral use
United Kingdom	Winthrop Pharmaceuticals UK Limited, One Onslow Street, Guildford, Surrey GU1 4YS United Kingdom	Sterwin Meds Co-codamol 8/500 tablets	Codeine phosphate + paracetamol	8mg + 500mg	tablet	oral use
United Kingdom	Winthrop Pharmaceuticals UK Limited, One Onslow Street, Guildford, Surrey GU1 4YS United Kingdom	Sterwin Meds Co-codamol 8/500 effervescent tablets	Codeine phosphate + paracetamol	8mg + 500mg	Tablet for oral solution	oral use
United Kingdom	Winthrop Pharmaceuticals UK Limited, One Onslow Street, Guildford, Surrey GU1 4YS United Kingdom	Sterwin Meds Co-codamol and caffeine soluble tablets	Codeine phosphate + paracetamol + caffeine	8mg + 500mg + 30mg	effervescent tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom	Winthrop Pharmaceuticals UK Limited, One Onslow Street, Guildford, Surrey GU1 4YS United Kingdom	Co-codamol tablets 15/500mg	Codeine phosphate hemihydrate + paracetamol	15mg + 500mg	tablet	oral use
United Kingdom	Winthrop Pharmaceuticals UK Limited, One Onslow Street, Guildford, Surrey GU1 4YS United Kingdom	Winthrop Pharms Co-codamol 8/500 tablets	Codeine phosphate hemihydrate + paracetamol	8mg + 500mg	tablet	oral use
United Kingdom	Winthrop Pharmaceuticals UK Limited, One Onslow Street, Guildford, Surrey GU1 4YS United Kingdom	Winthrop Pharms Co-codamol 8/500 effervescent tablets	Codeine phosphate hemihydrate + paracetamol	8mg + 500mg	effervescent tablet	oral use
United Kingdom	SSL INTERNATIONAL PLC (Reckitt Benckiser Group plc), Wescroft House, Wellcroft Road, Slough, Berkshire SL1 4AQ United Kingdom	SSL International Paracetamol, Codeine, Caffeine & Doxylamine Compound	Codeine phosphate + paracetamol + doxylamine succinate + caffeine	10mg + 450mg + 5mg + 30mg	tablet	oral use
United Kingdom	SSL INTERNATIONAL PLC (Reckitt Benckiser Group plc), Wescroft House, Wellcroft Road, Slough, Berkshire SL1 4AQ United Kingdom	Syndol	Codeine phosphate + caffeine + paracetamol + doxylamine succinate	10mg + 30 mg + 450mg + 5mg	Film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom	SSL INTERNATIONAL PLC (Reckitt Benckiser Group plc), Wescroft House, Wellcroft Road, Slough, Berkshire SL1 4AQ United Kingdom	Ibuprofen and codeine tablets 200mg/12.8mg	Codeine phosphate hemihydrate + ibuprofen	12.8mg + 200mg	tablet	oral use
United Kingdom	Bristol Laboratories Limited, Unit 3, Canalside, Northbridge Road, Berkhamsted, Hertfordshire HP4 1EG United Kingdom	Bristol Labs Co-codamol Tablets 8mg/500mg	Codeine phosphate + paracetamol	8mg + 500mg	tablet	oral use
United Kingdom	Bristol Laboratories Limited, Unit 3, Canalside, Northbridge Road, Berkhamsted, Hertfordshire HP4 1EG United Kingdom	Bristol Labs Codeine Phosphate Tablets 15mg	Codeine phosphate	15mg	tablet	oral use
United Kingdom	Bristol Laboratories Limited, Unit 3, Canalside, Northbridge Road, Berkhamsted, Hertfordshire HP4 1EG United Kingdom	Codeine Phosphate Tablets BP 30mg	Codeine phosphate	30mg	tablet	oral use
United Kingdom	Bristol Laboratories Limited, Unit 3, Canalside, Northbridge Road, Berkhamsted, Hertfordshire HP4 1EG United Kingdom	Co-codamol Tablets 30mg/500mg	Codeine phosphate + paracetamol	30mg + 500mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom	CRESCENT PHARMA LTD, Polhampton Lane, Units 3&4, Quidhampton Business units, Overton, Hampshire, RG25 3ED, United Kingdom	Co-codamol 500 mg/8 mg tablets	Codeine phosphate+paracetamol	8mg + 500mg	tablet	oral use
United Kingdom	CRESCENT PHARMA LTD, Polhampton Lane, Units 3&4, Quidhampton Business units, Overton, Hampshire, RG25 3ED, United Kingdom	codeine phosphate tablets BP 15mg	Codeine phosphate	15mg	tablet	oral use
United Kingdom	CRESCENT PHARMA LTD, Polhampton Lane, Units 3&4, Quidhampton Business units, Overton, Hampshire, RG25 3ED, United Kingdom	codeine phosphate tablets BP 30mg	Codeine phosphate	30mg	tablet	oral use
United Kingdom	CRESCENT PHARMA LTD, Polhampton Lane, Units 3&4, Quidhampton Business units, Overton, Hampshire, RG25 3ED, United Kingdom	codeine phosphate tablets BP 60mg	Codeine phosphate	60mg	tablet	oral use
United Kingdom	CRESCENT PHARMA LTD, Polhampton Lane, Units 3&4, Quidhampton Business units, Overton, Hampshire, RG25 3ED, United Kingdom	Co-codamol 500 mg/8 mg tablets	Codeine phosphate+paracetamol	8mg + 500mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom	FANNIN (UK) LIMITED, 42-46 Booth Drive, Park Farm South, Wellingborough NN8 6GT United Kingdom	Co-codamol 500 mg/30 mg tablets	Codeine phosphate+paracetamol	30mg + 500mg	effervescent tablet	oral use
United Kingdom	FANNIN (UK) LIMITED, 42-46 Booth Drive, Park Farm South, Wellingborough NN* 6GT United Kingdom	Co-codamol 500 mg/8 mg tablets	Codeine phosphate+paracetamol	8mg + 500mg	effervescent tablet	oral use
United Kingdom	FANNIN (UK) LIMITED, 42-46 Booth Drive, Park Farm South, Wellingborough NN* 6GT United Kingdom	Co-codamol 8/500 mg tablets	Codeine phosphate+paracetamol	8mg + 500mg	effervescent tablet	oral use
United Kingdom	FANNIN (UK) LIMITED, 42-46 Booth Drive, Park Farm South, Wellingborough NN* 6GT United Kingdom	Paracetamol, codeine +caffeine 500mg/8mg/30mg soluble tablets	Paracetamol + codeine phosphate hemihydrate+ caffeine	500mg + 8mg + 30mg	effervescent tablet	oral use
United Kingdom	AUROBINDO PHARMA LIMITED Ares Block, Odyssey Business Park, West End Road, South Ruislip HA4 6QD, United Kingdom	Codeine phosphate 15 mg tablets	Codeine phosphate	15mg	tablet	oral use
United Kingdom	AUROBINDO PHARMA LIMITED Ares Block, Odyssey Business Park, West End Road, South Ruislip HA4 6QD, United Kingdom	Codeine phosphate 30 mg tablets	Codeine phosphate	30mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom	AUROBINDO PHARMA LIMITED Ares Block, Odyssey Business Park, West End Road, South Ruislip HA4 6QD, United Kingdom	Codeine phosphate 60 mg tablets	Codeine phosphate	60mg	tablet	oral use
United Kingdom	CONSILIENT HEALTH LIMITED, 5th floor, Beaux Lane, Mercer Street Lower, Dublin 2, Ireland	Co-codamol 30/500 mg tablets	codeine phosphate+paracetamol	30mg + 500mg	effervescent tablet	oral use
United Kingdom	CONSILIENT HEALTH LIMITED, 5th floor, Beaux Lane, Mercer Street Lower, Dublin 2, Ireland	Co-codamol	codeine phosphate+paracetamol	8mg + 500mg	tablet	oral use
United Kingdom	CONSILIENT HEALTH LIMITED, 5th floor, Beaux Lane, Mercer Street Lower, Dublin 2, Ireland	Codeine phosphate 15 mg tablets	Codeine phosphate	15mg	tablet	oral use
United Kingdom	CONSILIENT HEALTH LIMITED, 5th floor, Beaux Lane, Mercer Street Lower, Dublin 2, Ireland	Codeine phosphate 30 mg tablets	Codeine phosphate	30mg	tablet	oral use
United Kingdom	CONSILIENT HEALTH LIMITED, 5th floor, Beaux Lane, Mercer Street Lower, Dublin 2, Ireland	Codeine phosphate 60 mg tablets	Codeine phosphate	60mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom	CONSILIENT HEALTH LIMITED, 5th floor, Beaux Lane, Mercer Street Lower, Dublin 2, Ireland	Cupanol Co-codamol	Codeine phosphate+paracetamol	8mg + 500mg	effervescent tablet	oral use
United Kingdom	Galen Limited, Seogoe Industiral Estate, Craigavon BT 63 5 UA, United Kingdom	Co-codamol 30MG/500MG	Codeine phosphate+paracetamol	30mg + 500mg	tablet	oral use
United Kingdom	Galen Limited, Seogoe Industiral Estate, Craigavon BT 63 5 UA, United Kingdom	Co-codamol 30MG/500MG	Codeine phosphate hemihydrate+paracetamol	30mg + 500mg	capsule, hard	oral use
United Kingdom	Galen Limited, Seogoe Industiral Estate, Craigavon BT 63 5 UA, United Kingdom	Kapake 15mg/500mg	Codeine phosphate hemihydrate+paracetamol	15mg + 500mg	tablet	oral use
United Kingdom	WOCKHARDT UK LIMITED Ash Road North, Wrexham Industrial Estate, Wrexham LL13 9UF, United Kingdom	Co-codamol 8MG/500MG	Codeine phosphate+paracetamol	8mg + 500mg	tablet	oral use
United Kingdom	WOCKHARDT UK LIMITED Ash Road North, Wrexham Industrial Estate, Wrexham LL13 9UF, United Kingdom	Co-codamol 30MG/500MG	Codeine phosphate+paracetamol	30mg + 500mg	tablet	oral use
United Kingdom	WOCKHARDT UK LIMITED Ash Road North, Wrexham Industrial Estate, Wrexham LL13 9UF, United Kingdom	Codeine phosphate 15 mg tablets	Codeine phosphate	15mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom	WOCKHARDT UK LIMITED Ash Road North, Wrexham Industrial Estate, Wrexham LL13 9UF, United Kingdom	Codeine phosphate 30 mg tablets	Codeine phosphate	30mg	tablet	oral use
United Kingdom	WOCKHARDT UK LIMITED Ash Road North, Wrexham Industrial Estate, Wrexham LL13 9UF, United Kingdom	Codeine phosphate 60 mg tablets	Codeine phosphate	60mg	tablet	oral use
United Kingdom	WOCKHARDT UK LIMITED Ash Road North, Wrexham Industrial Estate, Wrexham LL13 9UF, United Kingdom	Co-codamol 8/500 mg tablets	codeine phosphate+paracetamol	8mg + 500mg	tablet	oral use
United Kingdom	WOCKHARDT UK LIMITED Ash Road North, Wrexham Industrial Estate, Wrexham LL13 9UF, United Kingdom	Co-codamol 30/500 mg tablets	codeine phosphate+paracetamol	30mg + 500mg	tablet	oral use
United Kingdom	ACTAVIS GROUP PTC EHF Reykjavikurvegur 76-78 - 220 Hafnarfjörður Iceland	Co-codamol 8/500 mg tablets	codeine phosphate+paracetamol	8mg + 500mg	tablet	oral use
United Kingdom	MAX REMEDIES LIMITED, Stoney Gate House, 2 Greenfield Road, Holmfirth, West Yorkshire, HD9 2JT, United Kingdom	Max Remedies Clear Dissolving Pain Relief tablets	Codeine phosphate+paracetamol +caffeine	8mg +500mg + 30mg	effervescent tablet	ORAL USE

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom	CUSTOM HEALTHCARE, Conway street, Hove, East Sussex, BN3 3LW United Kingdom	custom Healthcare co-codamol 8/500mg capsules	Codeine phosphate+paracetamol	8mg + 500mg	capsule	oral use
United Kingdom	CUSTOM HEALTHCARE, Conway street, Hove, East Sussex, BN3 3LW United Kingdom	custom Healthcare co-codamol 8/500mg capsules	Codeine phosphate+paracetamol	8mg + 500mg	capsule	oral use
United Kingdom	CIPLA (EU) LIMITED, Hillbrow House, Hillbrow Road, Esher, Surrey, KT10 9NW United Kingdom	Co-codamol 8/500 mg tablets	Codeine phosphate+paracetamol	8mg + 500mg	tablet	oral use
United Kingdom	CIPLA (EU) LIMITED, Hillbrow House, Hillbrow Road, Esher, Surrey, KT10 9NW United Kingdom	Co-codamol 30/500 mg tablets	Codeine phosphate+paracetamol	30mg + 500mg	tablet	oral use
United Kingdom	CIPLA (EU) LIMITED, Hillbrow House, Hillbrow Road, Esher, Surrey, KT10 9NW United Kingdom	STD chemicals paracetamol codeine and caffeine	Codeine phosphate+paracetamol + caffeine	8mg + 500mg + 30mg	soluble tablet	oral use
United Kingdom	FOURRTS (UK)PHARMACARE LIMITED, 30 Chaul End Lane, Luton, Bedfordshire, LU4 8EZ, United Kingdom	Co-codamol tablets BP	Codeine phosphate+paracetamol	8mg + 500mg	tablet	oral use
United Kingdom	FOURRTS (UK)PHARMACARE LIMITED, 30 Chaul End Lane, Luton, Bedfordshire, LU4 8EZ, United Kingdom	Co-codaprin tablets B.P.	Codeine phosphate+Aspirin	8mg + 400mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN	Strength	Pharmaceutical form	Route of administration
United Kingdom	ZANZA LABORATORIES (HOLDINGS)LIMITED, Unit 2A Sefton Business Park, Aintree, Liverpool, L30 1RD, United Kingdom	Zanza Labs holdings Co-codamol	Codeine phosphate+paracetamol	30mg + 500mg	effervescent tablet	oral use
United Kingdom	ENNOGEN PHARMA LIMITED, Unit G4, Riverside Industrial Estate, Riverside Way, Dartford, DA1 5BS United Kingdom	Ennogen Pharma Co-codamol	Codeine phosphate+paracetamol	8mg +500 mg	effervescent tablet	oral use

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