

Annex I

List of the names, pharmaceutical forms, strengths of the medicinal products, routes of administration, marketing authorisation holders in the Member States

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Austria	Astellas Pharma GmbH Linzerstrasse 221 E02 1140 Wien Austria	Codeine	Codipertussin 697 mg/100 ml Konzentrat - Tropfen	697 mg/100 ml	Oral drops, suspension	Oral Use
Austria	Astellas Pharma GmbH Linzerstrasse 221 E02 1140 Wien Austria	Codeine	Codipertussin 230 mg/100 ml Hustensaft	230 mg/100 ml	Oral suspension	Oral Use
Belgium	Laboratoria Qualiphar N.V/S.A Rijksweg 9 2880 Bornem Belgium	Codeine phosphate hemihydrate	Bromophar	0.63mg/ml	Syrup	Oral use
Belgium	Medgenix Benelux n.v. Vliegveld 21 8560 Wevelgem Belgium	Codeine	Broncho- Pectoralis Codeine	1 mg/ml	Syrup	Oral use
Belgium	Laboratoires Belges Pharmacobel SA Avenue de Scheut, 46-50 1070 Brussels Belgium	Codeine phosphate hemihydrate	Bronchodine	2 mg/ml	Syrup	Oral use
Belgium	Johnson & Johnson Consumer NV/SA Antwerpseweg 15-17 2340 Beerse Belgium	Codeine phosphate hemihydrate	Bronchosedal codeine	0.92 mg/ml	Syrup	Oral use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Belgium	Laboratoria Qualiphar N.V./S.A Rijksweg 9 2880 Bornem Belgium	Codeine	Codeine siroop P.B.V./B.F.V.	2 mg/g	Syrup	Oral use
Belgium	Conforma NV Zenderstraat 10 9070 Destelbergen Belgium	Codeine	Codeinesiroop Eucalyptolsmaak Conforma	2.67 mg/ml	Syrup	Oral use
Belgium	Medgenix Benelux n.v. Vliegveld 21 8560 Wevelgem Belgium	Codeine	Codeinoform Medgenix	0.5 mg/ml	Syrup	Oral use
Belgium	Laboratoria Qualiphar N.V./S.A Rijksweg 9 2880 Bornem Belgium	Codeine	Codeinoform Qualiphar	0.5mg/g	Syrup	Oral use
Belgium	Laboratoria Qualiphar N.V./S.A Rijksweg 9 2880 Bornem Belgium	Codeine	Codocalyptol	1 mg/ml	Syrup	Oral use
Belgium	Medgenix Benelux n.v. Vliegveld 21 8560 Wevelgem Belgium	Codeine phosphate hemihydrate Eucalytol	Eucalytpine Lebrun Kinderen	5 mg 80 mg	Suppository	Rectal use

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Belgium	Medgenix Benelux n.v. Vliegveld 21 8560 Wevelgem Belgium	Codeine phosphate hemihydrate Eucalytol	Eucalytpine Lebrun volwassenen	20 mg 120 mg	Suppository	Rectal use
Belgium	Tilman sa Z.I Sud 15 5377 Baillonville Belgium	Codeine Sulfogaiacol	Eucalytux	1 mg/ml 20 mg/ml	Syrup	Oral use
Belgium	Meda Pharma sa Chaussée de la Hulpe, 166 1170 Brussels Belgium	Codeine phosphate hemihydrate	GlottyI	0.766 mg/ml	Syrup	Oral use
Belgium	Laboratoria Qualiphar N.V/S.A Rijksweg 9 2880 Bornem Belgium	Codeine phosphate hemihydrate Guaifenesin	Inalpin	0.632 mg/ml 6.32 mg/ml	Syrup	Oral use
Belgium	Conforma NV Zenderstraat 10 9070 Destelbergen Belgium	Codeine	Sirupus Codeini Conforma	2 mg/ml	Syrup	Oral use
Belgium	Laboratoria Qualiphar N.V/S.A Rijksweg 9 2880 Bornem Belgium	Codeine phosphate hemihydrate	Toularynx Codeine	0.77mg/ml	Syrup	Oral use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Belgium	Takeda Belgium SCA-CVA Gentsesteenweg 615 1080 Brussels Belgium	Codeine phosphate hemihydrate	Toux-San Codeine suikervrij	1 mg/ml	Syrup	Oral use
Cyprus	M S Jacovides & Co Ltd 8 Ayios Nicolaos Street Lefkosia 1511 Cyprus	Codeine phosphate Ephedrine hydrochloride Ammonium chloride Carbinoxamine maleate	Dulsana with codeine liquid	2 mg 0.8 mg 20 mg 0.4 mg	Syrup	Oral use
Cyprus	Omega Pharma Hellas S.A. 19th km Nat. Road Athens-Lamia New Erythraia Greece 14671	Paracetamol Codeine phosphate hemihydrate Caffeine	SOLPADEINE SOLUBLE TABLET	500 mg 8 mg 30 mg	Effervescent tablet	Oral use
Cyprus	Omega Pharma Hellas S.A. 19th km Nat. Road Athens-Lamia New Erythraia Greece 14671	Paracetamol Codeine phosphate hemihydrate Caffeine	SOLPADEINE TABLET	500 mg 8 mg 30 mg	Tablet	Oral use
Cyprus	George Petrou Ltd 50 Areos Street 2234 Latsia Nicosia Cyprus	Codeine phosphate Paracetamol Caffeine Sodium ascorbate Phenylephrine hydrochloride Ascorbic acid Diphennydramine hydrochloride	Uniflu with Gregovite C	10 mg 500 mg 30 mg 155.54 mg 10 mg 144.46 mg 15 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Czech Republic	Zentiva a.s. Einsteinova 24 851 01 Bratislava Slovak Republic	Codeine phosphate hemihydrate	Codein Slovakofarma 15 mg	14.36 mg	Tablet	Oral Use
Czech Republic	Zentiva a.s. Einsteinova 24 851 01 Bratislava Slovak Republic	Codeine phosphate hemihydrate	Codein Slovakofarma 30 mg	28.72 mg	Tablet	Oral Use
Czech Republic	TEVA Czech Industries s.r.o. Ostravská 305/29 74770 Opava - Komárov Czech Republic	Codeine phosphate hemihydrate Thyme liquid extract Quillaja saponin Aconite tincture Sweet orange tincture	Pleumolysin	3.06 mg/ml 30 mg/ml 5 mg/ml 40 mg/ml 150 mg/ml	Oral drops, solution	Oral Use
Czech Republic	Zentiva k.s. U Kabelovny 130 Dolni Mecholupy 102 37 Prague 10 Czech Republic	Paracetamol Codeine phosphate hemihydrate	Korylan	325 mg 28.73 mg	Tablet	Oral Use
Czech Republic	GlaxoSmithKline Consumer Healthcare, GlaxoSmithKline Export Ltd. Great West Road 980 Middlesex TW8 9GS Brentford United Kingdom	paracetamol caffeine codeine phosphate hemihydrate	Panadol Ultra	500 mg 30 mg 8 mg	Tablet	Oral Use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Czech Republic	GlaxoSmithKline Consumer Healthcare, GlaxoSmithKline Export Ltd. Great West Road 980 Middlesex TW8 9GS Brentford United Kingdom	paracetamol caffeine codeine phosphate hemihydrate	Panadol Ultra Rapide	500 mg 30 mg 8 mg	Effervescent tablet	Oral Use
Denmark	Alternova A/S Lodshusvej 11 DK-4230 Skælskør Denmark	Codeine	Kodein "Alternova"	25 mg	Film-coated tablet	Oral use
Denmark	Takeda Pharma A/S Dybendal Alle 10 2630 Taastrup Denmark	Codeine	Kodein "DAK"	3 mg/ml	Oral solution	Oral use
Denmark	Takeda Pharma A/S Dybendal Alle 10 DK-2630 Taastrup Denmark	Codeine	Kodein "DAK"	25 mg	Film-coated tablet	Oral use
Denmark	Amgros I/S Dampfærgevej 22 DK-2100 København Ø Denmark	Codeine	Kodein "SAD"	25 mg	Tablet	Oral use
Denmark	Takeda Pharma A/S Dybendal Alle 10 2630 Taastrup Denmark	Codeine	Kodein Stærk "DAK"	8 mg/ml	Oral solution	Oral use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Estonia	Actavis UK Limited Whiddon Valley, Barnstaple Devon, EX32 8NS United Kingdom	Paracetamol Codeine	CO-CODAMOL	500mg 8mg	Tablet	Oral use
Estonia	Omega Pharma Baltics SIA K. Ulmaņa gatve 119 Mārupe, LV-2167 Latvia	Paracetamol Codeine Caffeine	SOLPADEINE	500 mg 8 mg 30 mg	Tablet	Oral use
Estonia	Vitabalans Oy Varastokatu 8 13500 Hameenlinna Finland	Paracetamol Codeine	PARACETAMOL/C ODEINE VITABALANS	500 mg 30 mg	Tablet	Oral use
Estonia	Zentiva k.s. U Kabelovny 130 Dolni Mecholupy 102 37 Prague 10 Czech Republic	Paracetamol Codeine	ALGOCALM	500 mg 30 mg	Tablet	Oral use
Estonia	Omega Pharma Baltics SIA K. Ulmaņa gatve 119 Mārupe, LV-2167 Latvia	Paracetamol Codeine Caffeine	SOLPADEINE SOLUBLE	500 mg 8 mg 30 mg	Effervescent tablet	Oral use
Finland	Oy Leiras Takeda Pharmaceuticals AB Paciuksenkatu 21 PL 1406 00101 Helsinki Finland	Codeine phosphate hemihydrate Ephedrine Hydrochloride Diphenhydramine hydrochloride Cocillana	CODESAN COMP	3.13 mg 1.25 mg 1.25 mg 0.44 mg	Oral solution	Oral use

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Finland	Vitabalans Oy Varastokatu 8 13500 Hameenlinna Finland	Codeine phosphate hemihydrate Guaifenesin Ammonium chloride Thyme fluid extract	KATAPEKT	1 mg 20 mg 25 mg 60 mg	Oral solution	Oral use
Finland	Orion Oy Orionintie 1 PL 65 02101 Espoo Finland	Codeine phosphate hemihydrate Guaifenesin Ammonium chloride Thyme fluid extract	RECIPECT	0.958 mg 20 mg 25 mg 60 mg	Oral solution	Oral use
France	Laboratoires AMIDO 37, avenue Gabriel Péri BP 232 92503 Rueil-Malmaison Cedex France	Codeine phosphate hemihydrate	CODATUX ENFANTS, suppositoire	48 mg	Suppository	Rectal Use
France	LABORATOIRE HEPATOUM 1 bis, rue de Plaisance 94130 Nogent Sur Marne France	Codeine	EUCALYPTINE LE BRUN, sirop	122 mg/100 ml	Syrup	Oral Use
France	LABORATOIRES MAYOLY SPINDLER 6, avenue de l'Europe, BP 51, 78401 Chatou Cedex France	Codeine	EUPHON, sirop	1mg /1 ml	Syrup	Oral Use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
France	ZAMBON France 13, rue René Jacques 92138 Issy-les-Moulineaux Cedex France	Codeine phosphate hemihydrate	FLUDOUCIL, sirop	89 mg/100 ml	Syrup	Oral Use
France	BOUCHARA-RECORDATI 70, avenue Du Général De Gaulle Immeuble "Le Wilson" 92800 Puteaux France	Codeine	NEO-CODION ENFANTS, sirop	109.8 mg/100 ml	Syrup	Oral Use
France	Laboratoires AMIDO 37, avenue Gabriel Péri BP 232 92503 Rueil-Malmaison Cedex France	Codeine phosphate hemihydrate	NEOPECTYL ENFANTS, sirop	18 mg/100 ml	Syrup	Oral Use
France	Laboratoires AMIDO 37, avenue Gabriel Péri BP 232 92503 Rueil-Malmaison Cedex France	Codeine phosphate hemihydrate	RHINATUX, gélule	14.36 mg	Hard capsule	Oral Use
France	Laboratoires THERICA 15, avenue Henry Dunant 27400 Louviers France	Codeine	TUSSICALM ENFANTS 0,025 POUR CENT, sirop	25.6 mg /100 ml	Syrup	Oral Use

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France	Laboratoires THERICA 15, avenue Henry Dunant 27400 Louviers France	Codeine	TUSSIPAX, comprimé pelliculé	10 mg	Tablet	Oral Use
France	Laboratoires THERICA 15, avenue Henry Dunant 27400 Louviers France	Codeine	TUSSIPAX, sirop	50 mg/100 ml	Syrup	Oral Use
France	Laboratoires THERICA 15, avenue Henry Dunant 27400 Louviers France	Codeine	TUSSIPAX, solution buvable, gouttes	50 mg/100 ml	Oral solution	Oral Use
France	Pierre Fabre Médicament 45, Place Abel Gance 92654 Boulogne Billancourt France	Codeine	POLERY ADULTES SANS SUCRE, sirop édulcoré à la saccharine sodique et au cyclamate de sodium	11.8 mg/15 ml	Syrup	Oral Use
France	Pierre Fabre Médicament 45, Place Abel Gance 92654 Boulogne Billancourt France	Codeine	POLERY ADULTES, sirop	64 mg/100 ml	Syrup	Oral Use
Germany	AbZ-Pharma GmbH Graf-Arco-Str. 3 89079 Ulm Germany	Codeine phosphate hemihydrate	Codeinsaft-CT 5mg / 5ml	5 mg/5 ml	Oral solution	Oral Use

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Germany	AbZ-Pharma GmbH Graf-Arco-Str. 3 89079 Ulm Germany	Codeine phosphate hemihydrate	Codeintropfen-CT 1mg / Tropfen	2541 mg	Oral drops, solution	Oral Use
Germany	Aristo Pharma GmbH Wallenroder Str. 8-10 13435 Berlin Germany	Codeine phosphate hemihydrate	Tryasol Codein forte	3000 mg	Oral drops, solution	Oral Use
Germany	Aristo Pharma GmbH Wallenroder Str. 8-10 13435 Berlin Germany	Codeine phosphate hemihydrate	Tryasol Codein mite	290 mg	Oral solution	Oral Use
Germany	Berlin-Chemie AG Glienicke Weg 125 12489 Berlin Germany	Codeine phosphate hemihydrate	Codeinum phosphoricum Berlin-Chemie	30000 mg	Tablet	Oral Use
Germany	Cassella-med GmbH & Co. KG Gereonsmühlengasse 1 50670 Köln Germany	Codeine phosphate hemihydrate	Bronchicum Mono Codein Tropfen	3250 mg	Oral drops, solution	Oral Use
Germany	Desma GmbH Peter-Sander-Str. 41b 55252 Mainz-Kastel Germany	Codeine phosphate hemihydrate	Codeinum phosphoricum Compren 30mg	30.0 mg	Tablet	Oral Use

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Germany	Desma GmbH Peter-Sander-Str. 41b 55252 Mainz-Kastel Germany	Codeine phosphate hemihydrate	Codeinum phosphoricum Compren 50mg	50 mg	Tablet	Oral Use
Germany	Desma GmbH Peter-Sander-Str. 41b 55252 Mainz-Kastel Germany	Codeine phosphate hemihydrate	Codicompren 50mg retard	50 mg	Prolonged-release tablet	Oral Use
Germany	Hexal Aktiengesellschaft Industriestr. 25 83607 Holzkirchen Germany	Codeine phosphate hemihydrate	Codeintropfen HEXAL 0,5 mg/Tropfen Lösung zum Einnehmen	2300 mg	Oral drops, solution	Oral Use
Germany	MaxMedic Pharma GmbH Pasinger Str. 16 82166 Gräfelfing Germany	Codeine phosphate hemihydrate Codeine phosphate hemihydrate	Tussoret Tag- / Nacht kapseln	40.72 mg 67.87 mg	Capsule, hard	Oral Use
Germany	OPTIMED Pharma GmbH Alfred-Nobel-Str. 5 50226 Frechen Germany	Codeine phosphate hemihydrate	codi OPT	76.82 mg	Tablet	Oral Use

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Germany	TUSSIN Pharma GmbH Menchestr. 22a 35274 Kirchhain Germany	Codeine phosphate hemihydrate	Codipertussin mite Tabletten Codeinum phoph. 30 mg	30 mg	Tablet	Oral Use
Germany	TUSSIN Pharma GmbH Menchestr. 22a 35274 Kirchhain Germany	Codeine phosphate hemihydrate	Codipertussin Tabletten Codeinum phoph. 50 mg	50 mg	Tablet	Oral Use
Germany	TUSSIN Pharma GmbH Menchestr. 22a 35274 Kirchhain Germany	Codein Guaifenesin	Longtussin duplex Tag und Nacht N	35 mg 90 mg	Capsule, soft	Oral Use
Germany	UCB Pharma GmbH Alfred-Nobel-Str. 10 40789 Monheim Germany	Codeine	Codicaps mono 30 mg Weichkapsel	30 mg	Capsule, soft	Oral Use
Greece	Exelixis - Emporia Iatr. Eidon A.E L. Mesogion 501 153 43, Ag. Paraskevi Greece	Codeine phosphate Ephedrine Hydrochloride	Sival-B	7.5 mg/5 ml 5 mg/5 ml	Syrup	Oral Use
Hungary	PharmaSwiss Ceska Republika s.r.o. Jankovcova 1569/2c 17000 Praha 7 Czeh Republic	Codeine hydrochloride dihydrate Ephedrine hydrochloride	Coderetta N	5 mg 5 mg	Tablet	Oral Use

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Hungary	PharmaSwiss Ceska Republika s.r.o. Jankovcova 1569/2c 17000 Praha 7 Czech Republic	Codeine hydrochloride dihydrate Ephedrine hydrochloride	Coderit N	20 mg 20 mg	Tablet	Oral Use
Hungary	ExtractumPharma zrt. Megyeri út 64. Budapest, H-1044 Hungary	Codeine hydrochloride dihydrate Potassium guaiacolsulfonate hemihydrate sodium-hypophosphite calcium-hypophosphite	Erigon	44 mg 6180 mg 618 mg 2564 mg	Syrup	Oral Use
Hungary	GlaxoSmithKline Consumer Healthcare GlaxoSmithKline Export Ltd Brentford TW8 9GS United Kingdom	Paracetamol Codeine phosphate hemihydrate Caffeine	Panadol Ultra hard capsules	500 mg 8 mg 30 mg	Capsule, hard	Oral Use
Hungary	GlaxoSmithKline Consumer Healthcare GlaxoSmithKline Export Ltd Brentford TW8 9GS United Kingdom	Paracetamol Codeine phosphate hemihydrate Caffeine	Panadol Ultra effervescent tablets	500 mg 8 mg 30 mg	Effervescent tablet	Oral Use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Hungary	GlaxoSmithKline Consumer Healthcare GlaxoSmithKline Export Ltd Brentford TW8 9GS United Kingdom	Paracetamol Codeine phosphate hemihydrate Caffeine	Panadol Ultra tablets	500 mg 8 mg 30 mg	Tablet	Oral Use
Ireland	Pinewood Laboratories Ltd. Trading as Pinewood Healthcare Ballymacarbry Clonmel Co.Tipperary	Codeine phosphate	Codinex Codeine Phosphate 15mg/5ml Oral Solution	15 mg /5 ml	Oral Solution	Oral use
Ireland	Clonmel Healthcare Ltd Waterford Road Clonmel Co Tipperary Ireland	Paracetamol Codeine phosphate hemihydrate Caffeine	Maxilief Effervescent Tablets	500 mg 8 mg 30 mg	Effervescent tablet	Oral use
Ireland	Reckitt Benckiser Ireland Ltd. 7 Riverwalk Citywest Business Campus Dublin 24 Ireland	Ibuprofen Codeine phosphate hemihydrate	Nurofen Plus Tablets	200 mg 12.8 mg	Film-coated tablet	Oral use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Ireland	GlaxoSmithKline Consumer Healthcare (Ireland) Limited Stonemasons Way Rathfarnam Dublin 16 Ireland	Paracetamol Codeine phosphate hemihydrate	Panadeine Extra Strength Tablets	500 mg 12.8 mg	Film-coated tablet	Oral use
Ireland	Chefaro Ireland Limited First Floor, Block A The Crescent Building Northwood Office Park Dublin 9 Ireland	Paracetamol Codeine phosphate hemihydrate Caffeine	Solpadeine Capsules	500 mg 8 mg 30 mg	Capsule, hard	Oral use
Ireland	Chefaro Ireland Limited First Floor, Block A The Crescent Building Northwood Office Park Dublin 9 Ireland	Paracetamol Codeine phosphate hemihydrate Caffeine	Solpadeine Soluble Tablets	500 mg 8 mg 30 mg	Effervescent tablet	Oral use
Ireland	Chefaro Ireland Limited First Floor, Block A The Crescent Building Northwood Office Park Dublin 9 Ireland	Paracetamol Codeine phosphate hemihydrate Caffeine	Solpadeine Tablets	500 mg 8 mg 30 mg	Tablet	Oral use

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Ireland	Phoenix Labs Ltd Unit 12 Bunkilla Plaza Bracetown Business Park Clonee, Co. Meath Ireland	Paracetamol Codeine phosphate hemihydrate Caffeine Diphenhydramine hydrochloride Phenylephrine hydrochloride Ascorbic acid	Uniflu Plus with Vitamin C Tablets	500 mg 10 mg 30 mg 15 mg 10 mg 300 mg	Tablet	Oral use
Italy	Laboratorio Farmaceutico sit Specialita' Igienico Terapeutiche S.R.L. Via Cavour, 70 Mede 27035 Pavia Italy	Codeine hydrobromide Ederagenina	HEDERIX PLAN	600 mg/30ml 4500 mg/30ml	Oral drops, solution	Oral use
Italy	Laboratorio Farmaceutico sit Specialita' Igienico Terapeutiche S.R.L. Via Cavour, 70 Mede 27035 Pavia Italy	Codeine hydrobromide Ederagenina	HEDERIX PLAN	10 mg 180 mg	Suppository	Rectal use
Italy	A. Menarini Industrie Farmaceutiche Riunite S.r.l. Via Sette Santi, 3 50131 Firenze Italy	Codeine phosphate	BROMOCODEINA	7.5mg/5ml	Syrup	Oral use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Latvia	Herbapol Lublin S.A. ul. Diamentowa 25 20-471 Lublin Poland	Pine liquid extract Calcium lactate Fennel tincture Celandine liquid extract Codeine phosphate	Sirupus Pini compositus syrup	424 mg 64 mg 64 mg 10 mg 3 mg	Syrup	Oral Use
Latvia	Omega Pharma Baltics, SIA K.Ulmana 119 LV-2167 Marupe Latvia	Paracetamol Codeine Caffeine	Solpadeine 500 mg/8 mg/30 mg tablets	500 mg 8 mg 30 mg	Tablet	Oral use
Latvia	Omega Pharma Baltics, SIA K.Ulmana 119 LV-2167 Marupe Latvia	Paracetamol Codeine Caffeine	Solpadeine Soluble 500 mg/8 mg/30 mg soluble tablets	500 mg 8 mg 30 mg	Soluble tablet	Oral use
Lithuania	Omega Pharma Baltics, SIA K.Ulmana 119 LV-2167 Marupe Latvia	Paracetamol Codeine Caffeine	Solpadeine	500 mg 8 mg 30 mg	Tablet	Oral use
Lithuania	Omega Pharma Baltics, SIA K.Ulmana 119 LV-2167 Marupe Latvia	Paracetamol Codeine Caffeine	Solpadeine	500 mg 8 mg 30 mg	Soluble tablet	Oral use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Luxembourg	Laboratoria Qualiphar N.V/S.A Rijksweg 9 2880 Bornem Belgium	Codeine phosphate Hemihydrate Guaifenesin	Inalpin	9.48 mg/15 ml 94.8 mg/15 ml	Syrup	Oral use
Luxembourg	Laboratoria Qualiphar N.V/S.A Rijksweg 9 2880 Bornem Belgium	Codeine phosphate hemihydrate	Bromophar	9.5 mg/15 ml	Syrup	Oral use
Luxembourg	Johnson & Johnson Consumer NV/SA Antwerpseweg 15-17 2340 Beerse Belgium	Codeine phosphate hemihydrate	Bronchosedal codeine	0.92 mg/ml	Syrup	Oral use
Luxembourg	Meda Pharma sa Chaussée de la Hulpe, 166 1170 Brussels Belgium	Codeine phosphate hemihydrate	Glottyl	0.766 mg/ml	Syrup	Oral use
Luxembourg	BOUCHARA-RECORDATI 70, avenue Du Général De Gaulle Immeuble "Le Wilson" 92800 Puteaux France	Codeine	NEO-CODION ENFANTS, sirop	109.8 mg/100 ml	Syrup	Oral Use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Luxembourg	Laboratoria Qualiphar N.V/S.A Rijksweg 9 2880 Bornem Belgium	Codeine phosphate hemihydrate	Toularynx Codeine	11.49 mg/15 ml	Syrup	Oral use
Luxembourg	Takeda Belgium SCA-CVA Gentsesteenweg 615 1080 Brussels Belgium	Codeine phosphate hemihydrate	Toux-San Codeine	1 mg/ml	Syrup	Oral use
Malta	L.C.M. Limited Linthwaite, Huddersfield, West Yorkshire, HD7 5QH United Kingdom.	Codeine Phosphate	Codeine Linctus BP	15mg/5ml	Oral solution	Oral use
Malta	Alliance Pharmaceuticals Avonbridge House Bath Road, Chippenham Wiltshire, SN15 2BB United Kingdom	Caffeine Codeine Phosphate Diphenhydramine Hydrochloride Paracetamol Phenylephrine Hydrochloride	Uniflu with Vitamin C Tablets	30 mg 10 mg 15 mg 500 mg 10 mg	Film-coated tablet	Oral use
Malta	Chefaro Ireland Limited First Floor, Block A The Crescent Building Northwood Office Park Dublin 9 Ireland	Paracetamol Codeine phosphate hemihydrate Caffeine	Solpadeine Soluble Tablets	500 mg 8 mg 30 mg	Effervescent tablet	Oral use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Malta	M&A Pharmachem Limited Allenby Laboratories Wigan Road, Westhoughton Bolton BL5 2AL United Kingdom	Paracetamol Codeine phosphate	Co-Codamol Tablets BP 8/500mg	500 mg 8 mg	Tablet	Oral use
Poland	Herbapol - Lublin S.A. ul. Diamentowa 25 20-471 Lublin Poland	Pines extract fluid Fennel dye Codeine phosphate hemihydrate	HERBAPini	442 mg/5 ml 64 mg/5 ml 3 mg/5 ml	Syrup	Oral Use
Poland	Wrocławskie Zakłady Zielarskie "Herbapol" S.A. ul. Św. Mikołaja 65/68 50-951 Wrocław Poland	Thyme plant pulveratum Codeine Phosphorus hemihydricus	Neoazarina	316 mg 10 mg	Film-coated tablet	Oral Use
Poland	Wrocławskie Zakłady Zielarskie "Herbapol" S.A. ul. Św. Mikołaja 65/68 50-951 Wrocław Poland	Pines extract fluid Fennel dye Codeine phosphate hemihydrate	Sirupus Pini compositus	440 mg/5 ml 64 mg/5 ml 3.2 mg/5 ml	Syrup	Oral Use
Poland	Aflofarm Farmacja Polska Sp. z o.o. ul. Partyzancka 133/151 95-200 Pabianice Poland	Pines extract fluid Anise dye Codeine phosphate hemihydrate	Syrop sosnowy złożony Aflofarm	1283.1 mg/15 ml 194.4 mg/15 ml 9.72 mg/15 ml	Syrup	Oral Use

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Poland	Zakłady Farmaceutyczne "UNIA" Spółdzielnia Pracy ul. Chłodna 56/60 00-872 Warszawa Poland	Codeine Phosphate Hemihydrate Sulfogaiacol	Thiocodin	15 mg 300 mg	Tablet	Oral Use
Poland	Zakłady Farmaceutyczne "UNIA" Spółdzielnia Pracy ul. Chłodna 56/60 00-872 Warszawa Poland	Codeine Phosphate Hemihydrate Sulfogaiacol	Thiocodin	15 mg/10 ml 300 mg/10 ml	Syrup	Oral Use
Poland	Zakłady Farmaceutyczne POLPHARMA S.A. Pelplińska 19 83-200 Starogard Gdański Poland	Acetylsalicylic Acid Codeine phosphate	Ascodan	400 mg 8 mg	Tablet	Oral Use
Poland	Reckitt Benckiser (Poland) S.A. Okunin 1 05-100 Nowy Dwór Mazowiecki Poland	Ibuprofen Codeine phosphate	Nurofen Plus	200 mg 12.8 mg	Film-coated tablet	Oral Use
Poland	Omega Pharma Poland Sp. z o.o. Al.Niepodległości 18 02-653 Warszawa Poland	Paracetamol Codeine phosphate Caffeine	Solpadeine	500 mg 8 mg 30 mg	Effervescent tablet	Oral Use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Poland	Omega Pharma Poland Sp. z o.o. Al.Niepodległości 18 02-653 Warszawa Poland	Paracetamol Codeine phosphate Caffeine	Solpadeine	500 mg 8 mg 30 mg	Tablet	Oral Use
Poland	Omega Pharma Poland Sp. z o.o. Al.Niepodległości 18 02-653 Warszawa Poland	Paracetamol Codeine phosphate Caffeine	Solpadeine	500 mg 8 mg 30 mg	Capsule	Oral Use
Portugal	Ferraz Lynce, S.A. Rua Consiglieri Pedroso 123 - Queluz de Baixo P.O. Box 1001 2734-501 Barcarena Portugal	Codeine Phenyltoloxamine	Codipront	30 mg 10 mg	Capsule, hard	Oral use
Portugal	Ferraz Lynce, S.A. Rua Consiglieri Pedroso 123 - Queluz de Baixo P.O. Box 1001 2734-501 Barcarena Portugal	Codeine Phenyltoloxamine	Codipront	2.22 mg/ml 0.733 mg/ml	Syrup	Oral use
Portugal	Confar - Consórcio Farmacêutico, Lda. Rua Félix Correia, 1-B 1500-271 Lisboa Portugal	Codeine Potassium guaiacolsulfonate Sodium benzoate	Codol	10 mg 50 mg 100 mg	Coated tablet	Oral use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Portugal	ITF Healthvita, Unipessoal Lda Rua Consiglieri Pedroso 123 - Queluz de Baixo 2730-056 Barcarena Portugal	Codeine	Toseina	2 mg/ml	Oral solution	Oral use
Romania	S.C. MAGISTRA C & C S.R.L. Bd-ul Aurel Vlaicu nr. 82 A Constanța, cod postal 900055 România	Codeine phosphate	CODEINĂ FOSFAT MCC 15 mg	15 mg	Tablet	Oral Use
Romania	FARMACOM S.A. Str. Zizinului Nr. 112 cod postal 500407 Braşov România	Codeine phosphate	FARMACOD	15 mg	Tablet	Oral Use
Romania	SINTOFARM SA Str. Ziduri intre Vii nr. 22 Sector 2 Bucuresti, Cod postal 023324 Romania	Codeine phosphate	FOSFAT DE CODEINĂ 15 mg	15 mg	Tablet	Oral Use
Romania	SLAVIA PHARM S.R.L. B-dul Theodor Pallady, nr. 44C Sector 3 cod postal 032266, Bucureşti Romania	Codeine phosphate	CODEINĂ FOSFAT 15mg	15 mg	Tablet	Oral Use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Romania	S.C. BIO EEL S.R.L. Str. Bega Nr. 4, Târgu-Mureș cod postal 540390 România	Codeine phosphate	CODEINĂ FOSFORICĂ	15 mg	Tablet	Oral Use
Romania	S.C. LABORMED PHARMA S.A., ROMANIA Bd. Theodor Pallady nr. 44B sector 3, București Romania	Codeine phosphate	CODEINĂ FOSFAT LPH 15 mg	15 mg	Tablet	Oral Use
Romania	S.C. ARENA GROUP S.A. Str. Ștefan Mihăileanu nr. 31 Sector 2 București, cod postal 024022 România	Codeine phosphate Potassium guaiacolsulfonate	TUSOCALM 7,5mg/120mg	7.5 mg 120 mg	Tablet	Oral Use
Slovak Republic	Zentiva a.s. Einsteinova 24 851 01 Bratislava Slovak Republic	Codeine	Codein - SLOVAKOFARMA 15 mg	15 mg	Tablet	Oral Use
Slovak Republic	Zentiva a.s. Einsteinova 24 851 01 Bratislava Slovak Republic	Codeine	Codein - SLOVAKOFARMA 30 mg	30 mg	Tablet	Oral Use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Slovak Republic	TEVA Czech Industries s.r.o. Ostravská 305/29 74770 Opava - Komárov Czech Republic	Saponin Saponaria Codeine Aconite tincture Aurantii amari pericarpium tincture Thyme fluid extract	PLEUMOLYSIN	5 mg/1 ml 3.06 mg/1 ml 40 mg/1 ml 150 mg/1 ml 30 mg/1 ml	Oral drops, solution	Oral Use
Slovak Republic	Zentiva k.s. U Kabelovny 130 Dolni Mecholupy 102 37 Prague 10 Czech Republic	Paracetamol Codeine	Korylan	325 mg 21.17 mg	Tablet	Oral Use
Slovak Republic	GlaxoSmithKline Consumer Healthcare, GlaxoSmithKline Export Ltd. Great West Road 980 Middlesex TW8 9GS Brentford United Kingdom	Paracetamol Caffeine Codeine	Panadol Ultra	500 mg 30 mg 8 mg	Tablet	Oral Use
Slovak Republic	GlaxoSmithKline Consumer Healthcare, GlaxoSmithKline Export Ltd. Great West Road 980 Middlesex TW8 9GS Brentford United Kingdom	Paracetamol Caffeine Codeine	Panadol Ultra	500 mg 30 mg 8 mg	Capsule	Oral Use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Slovak Republic	GlaxoSmithKline Consumer Healthcare, GlaxoSmithKline Export Ltd. Great West Road 980 Middlesex TW8 9GS Brentford United Kingdom	Paracetamol Caffeine Codeine	Panadol Ultra Rapide	500 mg 30 mg 8 mg	Effervescent tablet	Oral Use
Slovenia	ALKALOID-INT d.o.o. Šlandrova ulica 4 1231 Ljubljana-Črnuče Slovenia	Codeine phosphate sesquihydrate	KODEINIJEV FOSFAT ALKALOID-INT 30 mg tablete	30 mg	Tablet	Oral use
Spain	Laboratorio Estedi, S.L. Montseny, 41 08012 Barcelona Spain	Codeine phosphate	Histaverin 10 mg/5 ml jarabe	10 mg/5 ml	Syrup	Oral use
Spain	Laboratorios Asociados Nupel, S.L. Rua Carpinteiros, 25 Polígono Industrial Ceao 27003 Lugo Spain	Codeine phosphate	Perduretas Codeina	50 mg	Tablet	Oral use
Spain	Laboratorios Viñas, S.A. Provenza, 386 08025 Barcelona Spain	Codeine phosphate hemihydrate Clorciclicine hydrochloride Eucalyptol Guaifenesin	Diminex Antitusígeno Infantil supositorios	5 mg 5 mg 50 mg 50 mg	Suppository	Rectal use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	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	Codeine phosphate hemihydrate	Codeisan 28,7 mg comprimidos	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	Codeine phosphate hemihydrate	Codeisan jarabe	6.33 mg/5 ml	Syrup	Oral use
Spain	Faes Farma, S.A. Maximo Aguirre, 14 48940 Lamiaco-Lejona (Vizcaya) Spain	Codeine phosphate	Fludan Codeina 10mg/5 ml solución oral	10 mg/5 ml	Oral solution	Oral use
Spain	Italfarmaco, S.A. San Rafael, 3 28108 Alcobendas (Madrid) Spain	Codeine phosphate hemihydrate	Toseina solución oral	10 mg/5 ml	Oral solution	Oral use
Spain	Faes Farma, S.A. Maximo Aguirre, 14 48940 Lamiaco-Lejona (Vizcaya) Spain	Codeine phosphate Pseudoephedrine hydrochloride Clorpheniramine maleate	Lasa con Codeina solución oral	10 mg/ 5 ml 30 mg/ 5 ml 2 mg / 5 ml	Oral solution	Oral use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Spain	Laboratorios Cinfa, S.A. Olaz-Chipi, 10 Polígono Industrial Areta 31620 Huarte-Pamplona (Navarra) Spain	Codeine phosphate Ephedrine hydrochloride Benzoate sodium Thiamine hydrochloride Pyridoxine hydrochloride Sulfoguaiacolate potassium Citrate acid sodium Menthol Drosera tincture Grindelia tincture Lobelia inflata tincture Oregano tincture	Pazbronquial jarabe	5 mg/5 ml 5 mg/ 5 ml 83 mg/ 5 ml 1 mg/ 5 ml 3 mg/ 5 ml 100 mg/ 5 ml 17 mg/ 5 ml 1 mg/ 5 ml 33 mg/ 5 ml 33 mg/ 5 ml 25 mg/ 5 ml 10 mg / 5 ml	Syrup	Oral use
Spain	Boehringer Ingelheim Espana, S.A. Prat de la Riba, 50 08174 Sant Cugat del Vallés (Barcelona) Spain	Codeine hydrochloride	Bisoltus 2 mg/ml solución oral	2 mg/ml	Oral solution	Oral use
Spain	Laboratorio Medea, S.A. Gran Capitán, 10 08970 Sant Joan Despi (Barcelona) Spain	Codeine phosphate hemihydrate	Notusin solución oral	10 mg/5 ml	Oral solution	Oral use
Spain	Kern Pharma, S.L Venus 72 Polígono Industrial Colón II 08228 Tarrasa (Barcelona) Spain	Acetylsalicylic Acid Codeine phosphate hemihydrate Cafeine	Dolvirán comprimidos	400 mg 9.6 mg 50 mg	Tablet	Oral Use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Spain	Kern Pharma, S.L Venus 72 Polígono Industrial Colón II 08228 Tarrasa (Barcelona) Spain	Acetylsalicylic Acid Codeine phosphate hemihydrate Cafeine	Dolvirán supositorios	400 mg 9.6 mg 50 mg	Suppository	Rectal use
Spain	Kern Pharma, S.L Venus 72 Polígono Industrial Colón II 08228 Tarrasa (Barcelona) Spain	Codeine phosphate hemihydrate	Tusikern 2 mg/ml solución oral EFG	2 mg/ml	Oral solution	Oral use
The Netherlands	OJG Consumer Care B.V Keyersweg 20 2201 CW Noordwijk The Netherlands	Codeine phosphate hemihydrate	Natterman Melrosum Extra Sterk, stroop	0.5 mg/ml	Syrup	Oral Use
The Netherlands	Ratiopharm Nederland B.V. Swensweg 5 2031 GA Haarlem The Netherlands	Codeine phosphate hemihydrate	Codeïnefosfaat ratiopharm 10 mg, tabletten	10 mg	Tablet	Oral Use
The Netherlands	Ratiopharm Nederland B.V. Swensweg 5 2031 GA Haarlem The Netherlands	Codeine phosphate hemihydrate	Codeïnefosfaat ratiopharm 20 mg, tabletten	20 mg	Tablet	Oral Use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
The Netherlands	Pharmachemie B.V. Swensweg 5 2031 GA Haarlem The Netherlands	Codeine phosphate hemihydrate	Codeinefosfaat 10 PCH, tabletten 10 mg	10 mg	Tablet	Oral Use
The Netherlands	Pharmachemie B.V. Swensweg 5 2031 GA Haarlem The Netherlands	Codeine phosphate hemihydrate	Codeinefosfaat 15 PCH, tabletten 15 mg	15 mg	Tablet	Oral Use
The Netherlands	Pharmachemie B.V. Swensweg 5 2031 GA Haarlem The Netherlands	Codeine phosphate hemihydrate	Codeinefosfaat 20 PCH, tabletten 20 mg	20 mg	Tablet	Oral Use
United Kingdom	Wise Pharmaceuticals Limited 7 Oxford Street Manchester M1 4PB United Kingdom	Codeine phosphate	Codeine Phosphate Oral Solution BP	25 mg/5 ml	Oral solution	Oral Use
United Kingdom	Wise Pharmaceuticals Limited 7 Oxford Street Manchester M1 4PB United Kingdom	Codeine phosphate	Codeine Linctus BP	15 mg/5 ml	Oral solution	Oral Use
United Kingdom	Actavis UK Limited Whiddon Valley, Barnstaple Devon, EX32 8NS United Kingdom	Codeine phosphate	Codeine Phosphate Tablets BP 15mg	15 mg	Tablet	Oral Use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
United Kingdom	Actavis UK Limited Whiddon Valley, Barnstaple Devon, EX32 8NS United Kingdom	Codeine phosphate	Codeine Phosphate Tablets BP 30mg	30 mg	Tablet	Oral Use
United Kingdom	Actavis UK Limited Whiddon Valley, Barnstaple Devon, EX32 8NS United Kingdom	Codeine phosphate	Codeine Phosphate Tablets BP 60mg	60 mg	Tablet	Oral Use