



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Division

Annex I

List of the names, pharmaceutical forms, strengths of the medicinal products, routes of administration, marketing authorisation holders in the member states for pholcodine-containing medicinal products

Article 107i of Directive 2001/83/EC

Procedure number: EMEA/H/A-107i/1521

Please note that this draft Annex I may be updated during the procedure to reflect any amended information on concerned products/MAHs.

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Member State in EEA	Marketing authorisation holder	Product name	INN + Strength	Pharmaceutical form	Route of administration
Belgium	Vemedia Manufacturing B. V.	Pholco-Méréprine Mono	Pholcodine 1mg/ml	syrup	oral use
Croatia	Alkaloid D.O.O.	Pholcodin Alkaloid	Pholcodine Monohydrate 10mg Capsule	capsule, hard	oral use
France	Biocodex	Dimetane Sans Sucre	Pholcodine 133mg/100ml	syrup	oral use
France	Biogaran	Pholcodine Biogaran	Pholcodine Monohydrate 131mg/100ml	syrup	oral use
France	Melisana Pharma	Broncalene Adultes	Chlorphenamine Maleate 0.0133g/100ml, Pholcodine 0.08g/100ml	syrup	oral use
France	Melisana Pharma	Broncalene Enfants	Chlorphenamine Maleate 0.01g/100ml, Pholcodine 0.05g/100ml	syrup	oral use
France	Zambon France S.A.	Biocalyptol	Pholcodine 131mg/100ml	syrup	oral use
France	Zambon France S.A.	Biocalyptol A La	Pholcodine 131mg/100ml, Guaiacol 19.75mg/100ml	syrup	oral use
France	Zambon France S.A.	Biocalyptol Sans Sucre	Pholcodine 131mg/100ml	syrup	oral use
Ireland	Glaxosmithkline Consumer Healthcare (Ireland) Ltd	Day Nurse	Pseudoephedrine Hydrochloride 30mg Capsule, Paracetamol 500mg Capsule, Pholcodine 5mg Capsule	capsule, hard	oral use
Ireland	Pinewood Laboratories Limited	Pholcodine Wockhardt UK	Pholcodine 1mg/ml	oral solution	oral use
Lithuania	Laboratoires Bouchara-Recordati	Hexapneumine Adults	Chlorphenamine Maleate 0.6mg/5ml, Bictymol 10mg/5ml, Pholcodine 6mg/5ml	syrup	oral use
Lithuania	Laboratoires Bouchara-Recordati	Hexapneumine Children	Chlorphenamine Maleate 0.5mg/5ml, Bictymol 7.5mg/5ml, Pholcodine 5mg/5ml	syrup	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN + Strength	Pharmaceutical form	Route of administration
Luxembourg	Vemedica Manufacturing B. V.	Pholco-Méréprine Mono	Pholcodine 1mg/ml	syrup	oral use
Slovenia	Alkaloid-Int D.O.O.	Folkodin Alkaloid-Int	Pholcodine Monohydrate 10mg Capsule	capsule, hard	oral use
United Kingdom (Northern Ireland)	Glaxosmithkline Consumer Healthcare (Uk) Trading Limited	Day & Night Nurse	Dextromethorphan Hydrobromide 7.5mg Capsule, Paracetamol 500mg Capsule, Pholcodine 5mg Capsule	capsule, hard	oral use
United Kingdom (Northern Ireland)	Glaxosmithkline Consumer Healthcare (Uk) Trading Limited	Day Nurse	Pseudoephedrine Hydrochloride 30mg Capsule, Paracetamol 500mg Capsule, Pholcodine 5mg Capsule	capsule, hard	oral use
United Kingdom (Northern Ireland)	Glaxosmithkline Consumer Healthcare (Uk) Trading Limited	Day Nurse	Pseudoephedrine Hydrochloride 60mg/30ml, Paracetamol 1000mg/30ml, Pholcodine 10mg/30ml	oral solution	oral use
United Kingdom (Northern Ireland)	Glaxosmithkline Consumer Healthcare (Uk) Trading Limited	Tixylix Dry Cough	Pholcodine 4mg/5ml	syrup	oral use
United Kingdom (Northern Ireland)	Infohealth Ltd	Hill's Balsam Dry Cough Liquid	Pholcodine 10mg/5ml	oral solution	oral use
United Kingdom (Northern Ireland)	Linthwaite Contract Manufacturing Ltd (L.C.M. Ltd.)	Pholcodine Linctus L.C.M.	Pholcodine Monohydrate 5mg/5ml	oral solution	oral use
United Kingdom (Northern Ireland)	Pinewood Laboratories Limited	Pholcodine Pinewood Laboratories Limited	Pholcodine 5mg/ml	oral solution	oral use
United Kingdom (Northern Ireland)	Pinewood Laboratories Limited	Pholcodine Wockhardt Uk Ltd	Pholcodine 2mg/ml	oral solution	oral use
United Kingdom (Northern Ireland)	The Boots Company Plc	Almus Cold And Flu Day Liquid	Pseudoephedrine Hydrochloride Bp 0.2%w/V, Pholcodine Ph. Eur. 0.033%w/V, Paracetamol Ph. Eur. 3.333%w/V	oral solution	oral use

Member State in EEA	Marketing authorisation holder	Product name	INN + Strength	Pharmaceutical form	Route of administration
United Kingdom (Northern Ireland)	The Boots Company Plc	Day Cold & Flu Relief	Pseudoephedrine Hydrochloride Bp 0.2%w/V, Pholcodine Ph. Eur. 0.033%w/V, Paracetamol Ph. Eur. 3.333%w/V	oral solution	oral use
United Kingdom (Northern Ireland)	The Boots Company Plc	Night Cough Relief	Diphenhydramine Hydrochloride Ph. Eur. 12.5mg/5ml, Pholcodine Ph. Eur. 3.75mg/5ml	oral solution	oral use
United Kingdom (Northern Ireland)	The Boots Company Plc	Dry Cough 6 Years +	Pholcodine Ph. Eur. 2mg/5ml	syrup	oral use
United Kingdom (Northern Ireland)	Thornton & Ross Ltd	Cofsed Paediatric	Pholcodine Monohydrate 0.4mg/ml	oral liquid	oral use
United Kingdom (Northern Ireland)	Thornton & Ross Ltd	Galenphol Paediatric	Pholcodine Monohydrate 0.4mg/ml	oral liquid	oral use
United Kingdom (Northern Ireland)	Thornton & Ross Ltd	Cofsed	Chlorphenamine Maleate 0.4mg/ml, Ephedrine Hydrochloride 1.6mg/ml, Pholcodine Monohydrate 1mg/ml	oral solution	oral use
United Kingdom (Northern Ireland)	Thornton & Ross Ltd	Covonia	Pholcodine Monohydrate 1mg/ml	oral solution	oral use
United Kingdom (Northern Ireland)	Thornton & Ross Ltd	Galenphol	Pholcodine Monohydrate 1mg/ml	oral solution	oral use
United Kingdom (Northern Ireland)	Thornton & Ross Ltd	Galenphol	Pholcodine Monohydrate 2mg/ml	oral solution	oral use
United Kingdom (Northern Ireland)	Thornton & Ross Ltd	Galenphol	Pholcodine Monohydrate 5mg/5ml	oral solution	oral use