



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 January 2016
EMA/72990/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: pholcodine

Procedure no.: PSUSA/00002396/201505



Product Name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Care Pholcodine 5mg/5ml Oral Solution Sugar Free		PL00240/0101	Thornton & Ross Ltd	United Kingdom
Cofsed Paediatric		PL 00240/0102	Thornton & Ross Ltd	United Kingdom
Covonia Dry Cough Sugar Free		PL00240/0353	Thornton & Ross Ltd	United Kingdom
Dimetane Sans Sucre		362 386-5 7 \$ 362 665-1 3	Biocodex	France
Dry Cough 6 Years +		PL 00014/0523	The Boots Company Plc	United Kingdom
Folkodin Alkaloid-Int		5363-I-1816/11	Alkaloid-Int D.O.O.	Slovenia
Folkodin Alkaloid-Int		5363-I-1817/11	Alkaloid-Int D.O.O.	Slovenia
Folkodin Alkaloid-Int		5363-I-1818/11	Alkaloid-Int D.O.O.	Slovenia
Galenphol Linctus		PL00240/0101	Thornton & Ross Ltd	United Kingdom
Galenphol Paediatric		PL 00240/0102	Thornton & Ross Ltd	United Kingdom
Galenphol Strong Linctus		PL00240/0103	Thornton & Ross Ltd	United Kingdom
Pholcodine Linctus		PL12965/0030	Thornton & Ross	United Kingdom
Pavacol-D		PL 16853/0100	Alliance Pharmaceuticals Limited	United Kingdom
Pholcodin Alkaloid		UP/I-530-09/12-02/54	Alkaloid D.O.O.	Croatia
Pholcodin Alkaloid		UP/I-530-09/12-02/56	Alkaloid D.O.O.	Croatia

Product Name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Pholcodin Za Djecu Alkaloid		UP/I-530-09/12-02/55	Alkaloid D.O.O.	Croatia
Pholcodine The Boots Company		PL 00014/5718R	The Boots Company Plc	United Kingdom
Tixylix Dry Cough		PL 00030/0090	Novartis Consumer Health (Uk) Limited	United Kingdom
Pholcodine Linctus BP		PL 04917/0002	Pinewood laboratories	United Kingdom
Strong Pholcodine Linctus BP		PL 04917/005	Pinewood laboratories	United Kingdom
Pholocodex 5mg/5ml Oral solution		PA 0281/004/001	Pinewood laboratories	Ireland
Codotussyl Toux Seche Adulte		34009 363 026 9 6 34009 366 846 0 7	Laboratoires Genevrier	France
Codotussyl Toux Seche Enfant		34009 341 824 3 3	Laboratoires Genevrier	France
BIOCALYPTOL, Sirop		357 215.1	ZAMBON France S.A	France
BIOCALYPTOL 6,55 mg/5 ml sans sucre®, sirop édulcoré à la saccharine sodique et au maltitol liquide		358 452-7	ZAMBON France S.A	France
FLUCALYPTOL TOUX SECHE PHOLCODINE 1,31 mg/ml, sirop		390 345.8 390 342-9 390 343-5 390 344-1	ZAMBON France S.A	France
FLUCALYPTOL TOUX SECHE PHOLCODINE 1,31 mg/ml SANS SUCRE		491 416-8 491 417-4 491 418-0 491 419-7	ZAMBON France S.A	France