



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 January 2020
EMA/178348/2020
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: pholcodine

Procedure no.: PSUSA/00002396/201905



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
HUMEX ADULTES TOUX SECHE PHOLCODINE, sirop	not available	356 211-2	LABORATOIRES URGO HEALTHCARE	FR
HUMEX ADULTES TOUX SECHE PHOLCODINE, sirop	not available	356 212-9	LABORATOIRES URGO HEALTHCARE	FR
HUMEX ENFANTS TOUX SECHE PHOLCODINE, sirop	not available	3400935621061	LABORATOIRES URGO HEALTHCARE	FR
BIOCALYPTOL 6,55 mg/5 ml SANS SUCRE, sirop édulcoré à la saccharine sodique et au maltitol liquide	not available	3400935844965	ZAMBON FRANCE S.A.	FR
BIOCALYPTOL 6,55 mg/5 ml SANS SUCRE, sirop édulcoré à la saccharine sodique et au maltitol liquide	not available	34009 358 450 4 7	ZAMBON FRANCE S.A.	FR
BIOCALYPTOL 6,55 mg/5 ml SANS SUCRE, sirop édulcoré à la saccharine sodique et au maltitol liquide	not available	34009 358 451 0 8	ZAMBON FRANCE S.A.	FR
BIOCALYPTOL 6,55 mg/5 ml SANS SUCRE, sirop édulcoré à la saccharine sodique et au maltitol liquide	not available	34009 358 452 7 6	ZAMBON FRANCE S.A.	FR
BIOCALYPTOL 6,55 mg/5 ml SANS SUCRE, sirop édulcoré à la saccharine sodique et au maltitol liquide	not available	34009 358 453 3 7	ZAMBON FRANCE S.A.	FR

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BIOCALYPTOL 6,55 mg/5 ml SANS SUCRE, sirop édulcoré à la saccharine sodique et au maltitol liquide	not available	34009 358 455 6 6	ZAMBON FRANCE S.A.	FR
BIOCALYPTOL 6,55 mg/5 ml SANS SUCRE, sirop édulcoré à la saccharine sodique et au maltitol liquide	not available	34009 358 456 2 7	ZAMBON FRANCE S.A.	FR
BIOCALYPTOL 6,55 mg/5 ml SANS SUCRE, sirop édulcoré à la saccharine sodique et au maltitol liquide	not available	34009 358 457 9 5	ZAMBON FRANCE S.A.	FR
Hill's Balsam Dry Cough Liquid	not available	PL 00415/0201	INFOHEALTH LABORATORIES LTD	UK
Tixylix Dry Cough	not available	PL 44673/0175	GLAXOSMITHKLINE CONSUMER HEALTHCARE (UK) TRADING LIMITED	UK
Superdrug Pholcodine Linctus BP	not available	PL 03105/0059	BELL SONS & CO (DRUGGISTS) LTD	UK
STRONG PHOLCODINE LINCTUS BP	not available	PL 03105/0060	BELL SONS & CO (DRUGGISTS) LTD	UK
Pholcodine Linctus Bell's Healthcare 5mg per 5ml Oral Solution	not available	PL 03105/0059	BELL SONS & CO (DRUGGISTS) LTD	UK
Morrison's Pholcodine Linctus Oral Solution	not available	PL 03105/0059	BELL SONS & CO (DRUGGISTS) LTD	UK
DIMETANE SANS SUCRE 133 mg/100 ml, sirop	not available	362 386-5	BIOCODEX	FR

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DIMETANE SANS SUCRE 133 mg/100 ml, sirop	not available	362 665-1	BIOCODEX	FR
HUMEX ADULTES TOUX SECHE PHOLCODINE, sirop	not available	356 211-2	LABORATOIRES URGO HEALTHCARE	FR
HUMEX ADULTES TOUX SECHE PHOLCODINE, sirop	not available	356 212-9	LABORATOIRES URGO HEALTHCARE	FR
HUMEX ENFANTS TOUX SECHE PHOLCODINE, sirop	not available	3400935621061	LABORATOIRES URGO HEALTHCARE	FR
Pholcodine Linctus BP	not available	PL 00014/5718R	THE BOOTS COMPANY PLC	UK
BIOCALYPTOL, sirop	not available	3400935721228	ZAMBON FRANCE S.A.	FR
BIOCALYPTOL, sirop	not available	34009 357 213 9 6	ZAMBON FRANCE S.A.	FR
BIOCALYPTOL, sirop	not available	34009 357 214 5 7	ZAMBON FRANCE S.A.	FR
BIOCALYPTOL, sirop	not available	34009 357 215 1 8	ZAMBON FRANCE S.A.	FR
Pholcodine Linctus BP	not available	PL 00014/5718R	THE BOOTS COMPANY PLC	UK
PHOLCODIN ALKALOID 10 mg tvrde kapsule	not available	HR-H-813937465	ALKALOID D.O.O.	HR
PHOLCODIN ALKALOID za djecu 4 mg/5 ml oralna otopina	not available	HR-H-134722630	ALKALOID D.O.O.	HR
PHOLCODIN ALKALOID 15 mg/15 ml oralna otopina	not available	HR-H-979030464	ALKALOID D.O.O.	HR
FOLKODIN ALKALOID-INT® 10 mg trde kapsule	not available	H/94/00644/003	ALKALOID-INT D.O.O.	SI
FOLKODIN ALKALOID-INT® 1 mg/ml peroralna raztopina	not available	H/94/00644/002	ALKALOID-INT D.O.O.	SI
FOLKODIN ALKALOID-INT® 0,8 mg/ml peroralna raztopina za otroke	not available	H/94/00644/001	ALKALOID-INT D.O.O.	SI

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CODOTUSSYL TOUX SECHE ENFANTS, sirop	not available	34009 341 824 3 3	LABORATOIRES GENEVRIER	FR
CODOTUSSYL TOUX SECHE ADULTES, sirop	not available	34009 362 026 9 6	LABORATOIRES GENEVRIER	FR
CODOTUSSYL TOUX SECHE ADULTES, sirop	not available	34009 366 846 0 7	LABORATOIRES GENEVRIER	FR