



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 September 2017
EMA/578638/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance(s): ursodeoxycholic acid

Procedure No.: PSUSA/00003084/201611



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
ADURSAL® 150 mg -tabletti, kalvopäällysteinen	not available	8952	TAKEDA OY	FI
ADURSAL® 150 mg, filmdragerad tablett	not available	8952	TAKEDA OY	FI
Bilifalk 250mg, Cápsulas duras	not available	64.342	DR FALK PHARMA GMBH	ES
Bilifalk 50 mg/ml suspensión oral	not available	79195	DR FALK PHARMA GMBH	ES
DELURSAN 250 mg, comprimé pelliculé	not available	34009 323 416 4 1	APTALIS PHARMA SAS	FR
DELURSAN 250 mg, comprimé pelliculé	not available	34009 385 726 7 4	APTALIS PHARMA SAS	FR
DELURSAN 500 mg, comprimé pelliculé sécable	not available	34009 219 312 1 1	APTALIS PHARMA SAS	FR
DESOXIL 150 mg compresse	not available	028336016	S.F. GROUP SRL	IT
DESOXIL 300 mg compresse	not available	028336028	S.F. GROUP SRL	IT
DESOXIL 450 mg compresse a rilascio prolungato	not available	028336042	S.F. GROUP SRL	IT
Destolit 150 mg tablets	not available	PL 00322/0076	NORGINE LIMITED	UK
DEURSIL 150 mg capsule rigide	not available	023605076	CHEPLAPHARM ARZNEIMITTEL GMBH	IT
DEURSIL 150 mg capsule rigide	not available	023605090	CHEPLAPHARM ARZNEIMITTEL GMBH	IT
DEURSIL 150 mg capsule rigide	not available	023605088	CHEPLAPHARM ARZNEIMITTEL GMBH	IT
DEURSIL 225 mg capsule rigide a rilascio prolungato	not available	023605165	CHEPLAPHARM ARZNEIMITTEL GMBH	IT
DEURSIL 225 mg capsule rigide a rilascio prolungato	not available	023605177	CHEPLAPHARM ARZNEIMITTEL GMBH	IT
DEURSIL 225 mg capsule rigide a rilascio prolungato	not available	023605140	CHEPLAPHARM ARZNEIMITTEL GMBH	IT
DEURSIL 225 mg capsule rigide a rilascio prolungato	not available	023605153	CHEPLAPHARM ARZNEIMITTEL GMBH	IT

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
Deursil 300 mg capsule rigide	not available	023605114	CHEPLAPHARM ARZNEIMITTEL GMBH	IT
Deursil 300 mg capsule rigide	not available	023605102	CHEPLAPHARM ARZNEIMITTEL GMBH	IT
Deursil 450 mg capsule rigide a rilascio prolungato	not available	023605138	CHEPLAPHARM ARZNEIMITTEL GMBH	IT
Deursil 450 mg capsule rigide a rilascio prolungato	not available	023605126	CHEPLAPHARM ARZNEIMITTEL GMBH	IT
DEURSIL 50 mg capsule rigide	not available	023605037	CHEPLAPHARM ARZNEIMITTEL GMBH	IT
DEURSIL 50 mg capsule rigide	not available	023605013	CHEPLAPHARM ARZNEIMITTEL GMBH	IT
DEURSIL 50 mg capsule rigide	not available	023605025	CHEPLAPHARM ARZNEIMITTEL GMBH	IT
LITOFF "300 mg compresse" 20 compresse divisibili	not available	028404010	I.B.N. SAVIO S.R.L.	IT
LITOFF "300 mg compresse" 20 compresse divisibili	not available	028404010	I.B.N. SAVIO S.R.L.	IT
LITOFF "450 mg compresse" 20 compresse	not available	028404034	I.B.N. SAVIO S.R.L.	IT
LITOFF "450 mg compresse" 20 compresse	not available	028404034	I.B.N. SAVIO S.R.L.	IT
LITOFF "450 mg compresse"- 20 compresse a rilascio prolungato	not available	028404022	I.B.N. SAVIO S.R.L.	IT
LITOFF "450 mg compresse"- 20 compresse a rilascio prolungato	not available	028404022	I.B.N. SAVIO S.R.L.	IT
Litursol 450 mg capsule rigide a rilascio prolungato	not available	024615092	CRINOS S.P.A.	IT
LITURSOL 150 mg compresse	not available	024615078	CRINOS S.P.A.	IT
LITURSOL 300 mg compresse	not available	024615080	CRINOS S.P.A.	IT

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
URSACOL 50 mg compresse	not available	023630015	ZAMBON ITALIA S.R.L.	IT
URSACOL 50 mg compresse	not available	023630027	ZAMBON ITALIA S.R.L.	IT
URSACOL 150 mg compresse	not available	023630039	ZAMBON ITALIA S.R.L.	IT
URSACOL 150 mg compresse	not available	023630041	ZAMBON ITALIA S.R.L.	IT
URSACOL 300 mg compresse	not available	023630054	ZAMBON ITALIA S.R.L.	IT
URSACOL 300 mg compresse	not available	023630066	ZAMBON ITALIA S.R.L.	IT
URSACOL 300 mg compresse	not available	023630078	ZAMBON ITALIA S.R.L.	IT
URSACOL 450 mg compresse a rilascio modificato	not available	023630092	ZAMBON ITALIA S.R.L.	IT
URSILON 150 mg capsule rigide	not available	024173078	IBI G. LORENZINI SPA	IT
URSILON 150 mg capsule rigide	not available	024173078	IBI G. LORENZINI SPA	IT
URSILON 150 mg capsule rigide	not available	024173078	IBI G. LORENZINI SPA	IT
URSILON 150 mg granuli per sospensione orale	not available	024173092	IBI G. LORENZINI SPA	IT
URSILON 150 mg granuli per sospensione orale	not available	024173092	IBI G. LORENZINI SPA	IT
URSILON 150 mg granuli per sospensione orale	not available	024173092	IBI G. LORENZINI SPA	IT
URSILON 300 mg capsule rigide	not available	024173080	IBI G. LORENZINI SPA	IT
URSILON 300 mg capsule rigide	not available	024173080	IBI G. LORENZINI SPA	IT
URSILON 300 mg capsule rigide	not available	024173080	IBI G. LORENZINI SPA	IT
URSILON 300 mg granuli per sospensione orale	not available	024173104	IBI G. LORENZINI SPA	IT
URSILON 300 mg granuli per sospensione orale	not available	024173104	IBI G. LORENZINI SPA	IT
URSILON 300 mg granuli per sospensione orale	not available	024173104	IBI G. LORENZINI SPA	IT
URSILON RETARD 225 mg capsule rigide a rilascio prolungato	not available	024173066	IBI G. LORENZINI SPA	IT

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
URSILON RETARD 225 mg capsule rigide a rilascio prolungato	not available	024173066	IBI G. LORENZINI SPA	IT
URSILON RETARD 225 mg capsule rigide a rilascio prolungato	not available	024173066	IBI G. LORENZINI SPA	IT
URSILON RETARD 450 mg capsule rigide a rilascio prolungato	not available	024173054	IBI G. LORENZINI SPA	IT
URSILON RETARD 450 mg capsule rigide a rilascio prolungato	not available	024173054	IBI G. LORENZINI SPA	IT
URSILON RETARD 450 mg capsule rigide a rilascio prolungato	not available	024173054	IBI G. LORENZINI SPA	IT
URSOBIL 150 mg capsule rigide	not available	024444 034	ABC FARMACEUTICI S.P.A.	IT
URSOBIL 150 mg capsule rigide	not available	024444 097	ABC FARMACEUTICI S.P.A.	IT
URSOBIL 250 mg capsule rigide	not available	024444 059	ABC FARMACEUTICI S.P.A.	IT
URSOBIL 250 mg capsule rigide	not available	024444 109	ABC FARMACEUTICI S.P.A.	IT
URSOBIL 300 mg compresse	not available	024444 123	ABC FARMACEUTICI S.P.A.	IT
URSOBIL 300 mg compresse	not available	024444 135	ABC FARMACEUTICI S.P.A.	IT
URSOBIL GOCCE 100 ml soluzione	not available	024444085	ABC FARMACEUTICI S.P.A.	IT
URSOBIL HT capsula rigida a rilascio modificato 225 mg	not available	029038015	ABC FARMACEUTICI S.P.A.	IT
URSOBIL HT capsula rigida a rilascio modificato 450 mg	not available	029038027	ABC FARMACEUTICI S.P.A.	IT
URSOBIL SCIROPPO 100 ml soluzione	not available	024444111	ABC FARMACEUTICI S.P.A.	IT
Ursochol 150 mg Tabletten	not available	1527.00.00	ZAMBON GMBH	DE
URSOCHOL 150 mg comprimate	not available	7582/2015/01	ZAMBON S.P.A.	RO
URSOCHOL 150 mg comprimate	not available	7582/2015/04	ZAMBON S.P.A.	RO
URSOCHOL 150 mg comprimate	not available	7582/2015/02	ZAMBON S.P.A.	RO
URSOCHOL 150 mg comprimate	not available	7582/2015/05	ZAMBON S.P.A.	RO
URSOCHOL 150 mg comprimate	not available	7582/2015/03	ZAMBON S.P.A.	RO
Ursochol 150 mg comprimés	not available	BE112497	ZAMBON NV	BE

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
Ursochol 150 mg comprimés	not available	0411/05088205	ZAMBON NV	LU
Ursochol 150 mg comprimidos	not available	56.119	ZAMBON, S.A.U.	ES
Ursochol 150 mg tabletten	not available	BE112497	ZAMBON NV	BE
Ursochol 150 mg tabletta	not available	OGYI-T-9656/01	ZAMBON S.P.A.	HU
Ursochol 150 mg tabletta	not available	OGYI-T-9656/02	ZAMBON S.P.A.	HU
Ursochol 150 mg tabletta	not available	OGYI-T-9656/03	ZAMBON S.P.A.	HU
Ursochol 150 mg tabletta	not available	OGYI-T-9656/04	ZAMBON S.P.A.	HU
Ursochol 150 mg tabletta	not available	OGYI-T-9656/05	ZAMBON S.P.A.	HU
Ursochol 150, TABLETTEN 150 mg	not available	RVG 07718	ZAMBON NEDERLAND B.V.	NL
URSOCHOL 300 mg comprimate	not available	7583/2015/01	ZAMBON S.P.A.	RO
URSOCHOL 300 mg comprimate	not available	7583/2015/02	ZAMBON S.P.A.	RO
URSOCHOL 300 mg comprimate	not available	7583/2015/04	ZAMBON S.P.A.	RO
URSOCHOL 300 mg comprimate	not available	7583/2015/03	ZAMBON S.P.A.	RO
URSOCHOL 300 mg comprimate	not available	7583/2015/05	ZAMBON S.P.A.	RO
Ursochol 300 mg comprimés	not available	BE175472	ZAMBON NV	BE
Ursochol 300 mg comprimés	not available	0411/02/01/6338	ZAMBON NV	LU
Ursochol 300 mg tabletten	not available	BE175472	ZAMBON NV	BE
Ursochol 300 mg tabletta	not available	OGYI-T-9656/06	ZAMBON S.P.A.	HU
Ursochol 300 mg tabletta	not available	OGYI-T-9656/07	ZAMBON S.P.A.	HU
Ursochol 300 mg tabletta	not available	OGYI-T-9656/08	ZAMBON S.P.A.	HU
Ursochol 300 mg tabletta	not available	OGYI-T-9656/09	ZAMBON S.P.A.	HU
Ursochol 300, TABLETTEN 300 mg	not available	RVG 09307	ZAMBON NEDERLAND B.V.	NL
Ursochol 300mg Tabletten	not available	37567.00.00	ZAMBON GMBH	DE
Ursochol 450 mg comprimés	not available	BE285241	ZAMBON NV	BE
Ursochol 450 mg tabletten	not available	BE285241	ZAMBON NV	BE
Ursochol 450, TABLETTEN 450 mg	not available	RVG 29828	ZAMBON NEDERLAND B.V.	NL
Ursochol 50 mg comprimés	not available	BE112481	ZAMBON NV	BE
Ursochol 50 mg tabletten	not available	BE112481	ZAMBON NV	BE
Ursochol 500 mg kapsler, harde	SE/H/1318/002	13-9748	ORIFARM GENERICS A/S	NO

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
Ursochol 600, tabletten 600 mg	not available	RVG 114131	ZAMBON NEDERLAND B.V.	NL
Ursofalk 250 mg/5ml belsőleges szuszpenzió	not available	OGYI-T-1620/02	DR FALK PHARMA GMBH	HU
Ursofalk 250 mg capsulas	not available	9632000	DR. FALK PHARMA PORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
Ursofalk 250 mg capsulas	not available	9632018	DR. FALK PHARMA PORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
Ursofalk 250 mg capsules	not available	MA02600201	DR FALK PHARMA GMBH	MT
Ursofalk 250 mg cietās kapsulas	not available	99-0861	DR FALK PHARMA GMBH	LV
Ursofalk 250 mg gélules	not available	BE116873	DR. FALK PHARMA BENELUX B.V.	BE
Ursofalk 250 mg gélules	not available	2010080857	DR. FALK PHARMA BENELUX B.V.	LU
Ursofalk 250 mg Hard capsules	not available	PA 573/5/1	DR FALK PHARMA GMBH	IE
Ursofalk 250 mg hårda kapslar	not available	12581	DR FALK PHARMA GMBH	SE
Ursofalk 250 mg harde capsules	not available	BE116873	DR. FALK PHARMA BENELUX B.V.	BE
Ursofalk 250 mg kemény kapszula	not available	OGYI-T-1620/01	DR FALK PHARMA GMBH	HU
Ursofalk 250 mg kietos kapsulės	not available	LT/1/96/1390/001	DR FALK PHARMA GMBH	LT
Ursofalk 250 mg trde kapsule	not available	H/02/01586/001 (PACK SIZE 50)	DR FALK PHARMA GMBH	SI
Ursofalk 250 mg trde kapsule	not available	H/02/01586/002 (PACK SIZE 100)	DR FALK PHARMA GMBH	SI
Ursofalk 250 mg tvrde kapsule	not available	HR-H-837713755	WURTH D.O.O.	HR
Ursofalk 250 mg/5 ml geriamoji suspensija	not available	LT/1/96/1390/002	DR FALK PHARMA GMBH	LT
Ursofalk 250 mg/5 ml peroralna suspenzija	not available	H/02/01586/005	DR FALK PHARMA GMBH	SI
Ursofalk 250 mg/5 ml suspensija iekšīgai lietošanai	not available	10-0013	DR FALK PHARMA GMBH	LV
Ursofalk 250 mg/5 ml suspenzia	not available	43/0543/08-S	DR FALK PHARMA GMBH	SK
Ursofalk 250mg capsule	not available	4373/2012/02 (PACK	DR FALK PHARMA GMBH	RO

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
		SIZE 100)		
Ursofalk 250mg capsule	not available	4373/2012/01 (PACK SIZE 50)	DR FALK PHARMA GMBH	RO
Ursofalk 250mg hard capsules	not available	PL 10341/0006	DR FALK PHARMA UK LTD	UK
Ursofalk 250mg Kapseln	not available	39200.00.00	DR FALK PHARMA GMBH	DE
Ursofalk 250mg/5ml suspensie orala	not available	4374/2012/02 (PACK SIZE 2)	DR FALK PHARMA GMBH	RO
Ursofalk 250mg/5ml suspensie orala	not available	4374/2012/01 (PACK SIZE 1)	DR FALK PHARMA GMBH	RO
Ursofalk 250mg/5ml Suspension	not available	39200.00.01	DR FALK PHARMA GMBH	DE
Ursofalk 250mg/5ml Suspension	not available	PL 10341/0007	DR FALK PHARMA UK LTD	UK
Ursofalk 50 mg/ml mikstur, suspensjon	not available	09-7280	DR FALK PHARMA GMBH	NO
Ursofalk 50 mg/ml oral suspension	not available	15579	DR FALK PHARMA GMBH	SE
Ursofalk 50 mg/ml suspensie	not available	RVG 101647	DR. FALK PHARMA BENELUX B.V.	NL
Ursofalk 500 mg apvalkotās tabletes	not available	10-0571	DR FALK PHARMA GMBH	LV
Ursofalk 500 mg comprimés pelliculés	not available	BE446444	DR. FALK PHARMA BENELUX B.V.	BE
Ursofalk 500 mg film-coated tablets	not available	PL 10341/0010	DR FALK PHARMA UK LTD	UK
Ursofalk 500 mg filmdragerad tablett	not available	42663	DR FALK PHARMA GMBH	SE
Ursofalk 500 mg filmdrasjerte tabletter	not available	09-7162	DR FALK PHARMA GMBH	NO
Ursofalk 500 mg filmom obalené tablety	not available	43/0317/10-S	DR FALK PHARMA GMBH	SK
Ursofalk 500 mg filmom obložene tablete	not available	UP/I-530-09/12-01/129	WURTH D.O.O.	HR
Ursofalk 500 mg filmomhulde tabletten	not available	BE446444	DR. FALK PHARMA BENELUX B.V.	BE
Ursofalk 500 mg filmomhulde tabletten	not available	RVG 112405	DR. FALK PHARMA BENELUX B.V.	NL

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
Ursofalk 500 mg filmsko obložene tablete	not available	H/02/01586/004 (PACK SIZE 100)	DR FALK PHARMA GMBH	SI
Ursofalk 500 mg filmsko obložene tablete	not available	H/02/01586/003 (PACK SIZE 50)	DR FALK PHARMA GMBH	SI
Ursofalk 500 mg filmtabletta	not available	OGYI-T-1620/04 (PACK SIZE: 100)	DR FALK PHARMA GMBH	HU
Ursofalk 500 mg filmtabletta	not available	OGYI-T-1620/03 (PACK SIZE: 50))	DR FALK PHARMA GMBH	HU
Ursofalk 500 mg plėvele dengtos tabletės	not available	LT/1/96/1390/003 (PACK SIZE 50)	DR FALK PHARMA GMBH	LT
Ursofalk 500 mg plėvele dengtos tabletės	not available	LT/1/96/1390/004 (PACK SIZE 100)	DR FALK PHARMA GMBH	LT
Ursofalk 500 mg potahované tablety	not available	43/822/11-C	DR FALK PHARMA GMBH	CZ
Ursofalk 500mg comprimate filmate	not available	4646/2012/02 (PACK SIZE 100)	DR FALK PHARMA GMBH	RO
Ursofalk 500mg comprimate filmate	not available	4646/2012/01 (PACK SIZE 50)	DR FALK PHARMA GMBH	RO
Ursofalk 500mg film-coated tablets	not available	PA 573/5/3	DR FALK PHARMA GMBH	IE
Ursofalk 500mg Filmtabletten	not available	54690.00.00	DR FALK PHARMA GMBH	DE
Ursofalk capsules	not available	9649	DR FALK PHARMA GMBH	CY
Ursofalk kapsel, hard 250mg	not available	98-2831	DR FALK PHARMA GMBH	NO
URSOFALK KAPSULY	not available	43/0397/92-S	DR FALK PHARMA GMBH	SK
Ursofalk kovakapsel 250mg	not available	349401	DR FALK PHARMA GMBH	EE
Ursofalk suspenze 250 mg/5 ml	not available	43/837/10-C	DR FALK PHARMA GMBH	CZ
Ursofalk suspenze 250 mg/5 ml	not available	43/837/10-C	DR FALK PHARMA GMBH	CZ
Ursofalk, 250 mg, kapsułki	not available	6899	DR FALK PHARMA GMBH	PL
Ursofalk, 250 mg/5 ml, zawiesina doustna	not available	18364	DR FALK PHARMA GMBH	PL

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
Ursofalk, 500 mg Comprimidios revestidos por película	not available	5631072	DR. FALK PHARMA PORTUGAL, SOCIEDADE UNIPessoal LDA.	PT
Ursofalk, 500 mg Comprimidios revestidos por película	not available	5631106	DR. FALK PHARMA PORTUGAL, SOCIEDADE UNIPessoal LDA.	PT
Ursofalk, 500 mg, tabletki powlekane	not available	18349	DR FALK PHARMA GMBH	PL
Ursofalk® 250 mg- Kapseln	not available	17.053	DR FALK PHARMA GMBH	AT
URSOFALK® 250 mg καψάκιο σκληρό	not available	42754/07/23-4-2008	GALENICA SA	GR
Ursofalk® 250 mg/5 ml - orale Suspension	not available	1-24109	DR FALK PHARMA GMBH	AT
URSOFALK® 250 mg/5 ml πόσιμο εναιώρημα	not available	42757/07/23-4-2008	GALENICA SA	GR
Ursofalk® 250mg / 5ml Suspension	not available	PA 573/5/2	DR FALK PHARMA GMBH	IE
Ursofalk® 250mg/5ml suspension	not available	20790	DR FALK PHARMA GMBH	CY
Ursofalk® 500 mg - Filmtabletten	not available	1-31196	DR FALK PHARMA GMBH	AT
URSOFALK®, capsules 250 mg.	not available	RVG 08384	DR. FALK PHARMA BENELUX B.V.	NL
URSOLISIN 150 mg capsule rigide	not available	025430063	MAGIS FARMACEUTICI SRL	IT
URSOLISIN 150 mg capsule rigide	not available	025430075	MAGIS FARMACEUTICI SRL	IT
URSOLISIN 150 mg capsule rigide	not available	025430087	MAGIS FARMACEUTICI SRL	IT
URSOLISIN 300 mg capsule rigide	not available	025430101	MAGIS FARMACEUTICI SRL	IT
URSOLISIN 300 mg capsule rigide	not available	025430099	MAGIS FARMACEUTICI SRL	IT
URSOLVAN 200 mg, gélule	not available	34009 323 407 5 0	CHEPLAPHARM ARZNEIMITTEL GMBH	FR
Ursosan 250 mg tvrdé tobolky	not available	87/178/92-C	PRO.MED.CS PRAHA A.S.	CZ
Ursosan 250mg Hartkapseln	not available	39225.00.00	DR FALK PHARMA GMBH	DE
URSULTEC 25 g/100 ml gocce orali, soluzione	not available	033944012	OTIFARMA S.R.L.	IT
URSULTEC 3 g/100 ml sciroppo	not available	033944024	OTIFARMA S.R.L.	IT
Урзофалк капсули	not available	9600066	DR FALK PHARMA GMBH	BG