9 April 2021
EMA/179938/2021
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: dexibuprofen

Procedure no.: PSUSA/00000996/202008

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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
Algoflex Neo 200 mg filmtabletta	AT/H/0112/001/E/002	OGYI-T-23677/02	SANOFI-AVENTIS ZRT	HU
Algoflex Neo 200 mg filmtabletta	AT/H/0112/001/E/002	OGYI-T-23677/04	SANOFI-AVENTIS ZRT	HU
Algoflex Neo 200 mg filmtabletta	AT/H/0112/001/E/002	OGYI-T-23677/06	SANOFI-AVENTIS ZRT	HU
Algoflex Neo 200 mg filmtabletta	AT/H/0112/001/E/002	OGYI-T-23677/08	SANOFI-AVENTIS ZRT	HU
Algoflex Neo 200 mg filmtabletta	AT/H/0112/001/E/002	OGYI-T-23677/10	SANOFI-AVENTIS ZRT	HU
Algoflex Neo 200 mg filmtabletta	AT/H/0112/001/E/002	OGYI-T-23677/01	SANOFI-AVENTIS ZRT	HU
Algoflex Neo 200 mg filmtabletta	AT/H/0112/001/E/002	OGYI-T-23677/03	SANOFI-AVENTIS ZRT	HU
Algoflex Neo 200 mg filmtabletta	AT/H/0112/001/E/002	OGYI-T-23677/05	SANOFI-AVENTIS ZRT	HU
Algoflex Neo 200 mg filmtabletta	AT/H/0112/001/E/002	OGYI-T-23677/07	SANOFI-AVENTIS ZRT	HU
Algoflex Neo 200 mg filmtabletta	AT/H/0112/001/E/002	OGYI-T-23677/09	SANOFI-AVENTIS ZRT	HU
Atriscal 200 mg - Filmtabletten	not available	1-31858	GEBRO PHARMA GMBH	AT
Atriscal 300 mg - Filmtabletten	not available	1-31859	GEBRO PHARMA GMBH	AT
ATRISCAL 300 mg comprimidos recubiertos con película	AT/H/0112/002	63.607	LABORATORIOS GEBRO PHARMA, S.A.	ES
Atriscal 400 mg - Filmtabletten	not available	1-31860	GEBRO PHARMA GMBH	AT
ATRISCAL 400 mg comprimidos recubiertos con película	AT/H/0112/003	63.606	LABORATORIOS GEBRO PHARMA, S.A.	ES
Buscofokus 200 mg compresse rivestite con film	AT/H/0112/001/E/002	047939044	SANOFI S.P.A	IT

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Buscofokus 200 mg compresse rivestite con film	AT/H/0112/001/E/002	047939018	SANOFI S.P.A	IT
Buscofokus 200 mg compresse rivestite con film	AT/H/0112/001/E/002	047939071	SANOFI S.P.A	IT
Buscofokus 200 mg compresse rivestite con film	AT/H/0112/001/E/002	047939032	SANOFI S.P.A	IT
Buscofokus 200 mg compresse rivestite con film	AT/H/0112/001/E/002	047939020	SANOFI S.P.A	IT
Buscofokus 200 mg compresse rivestite con film	AT/H/0112/001/E/002	047939057	SANOFI S.P.A	IT
Buscofokus 200 mg compresse rivestite con film	AT/H/0112/001/E/002	047939069	SANOFI S.P.A	IT
Deltaran® 300 mg Filmtabletten	AT/H/0112/002	49606.01.00	PHARMORE GMBH	DE
Deltaran® 400 mg Filmtabletten	AT/H/0112/003	49606.02.00	PHARMORE GMBH	DE
Dexibuprofen „Gebro" 300 mg - Filmtabletten	AT/H/0111/002	1-23571	GEBRO PHARMA GMBH	AT
Dexibuprofen „Gebro" 400 mg - Filmtabletten	AT/H/0111/003	1-23572	GEBRO PHARMA GMBH	AT
Dolomagon 400 mg Filmtabletten	AT/H/0111/003	49603.02.00	GEBRO PHARMA GMBH	DE
Eu-Med 200 mg Schmerztabletten	not available	1-21535	GEBRO PHARMA GMBH	AT
FENEXTRA "200 mg Granulato per sospensione orale"	not available	035512108	BRUNO FARMACEUTICI	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
FENEXTRA "300 mg Granulato per sospensione orale"	not available	035512072	BRUNO FARMACEUTICI	IT
FENEXTRA "400 mg Compresse rivestite con film"	not available	035512045	BRUNO FARMACEUTICI	IT
FENEXTRA "400 mg Granulato per sospensione orale"	not available	035512084	BRUNO FARMACEUTICI	IT
Ibolex 200 mg filmom obalené tablety	AT/H/0112/001	29/0094/20-S	SANOFI-AVENTIS SLOVAKIA SRO	SK
Ibolex 200 mg filmom obalené tablety	AT/H/0112/001	29/0094/20-S	SANOFI-AVENTIS SLOVAKIA SRO	SK
Ibolex 200 mg filmom obalené tablety	AT/H/0112/001	29/0094/20-S	SANOFI-AVENTIS SLOVAKIA SRO	SK
Ibolex 200 mg filmom obalené tablety	AT/H/0112/001	29/0094/20-S	SANOFI-AVENTIS SLOVAKIA SRO	SK
Ibolex 200 mg filmom obalené tablety	AT/H/0112/001	29/0094/20-S	SANOFI-AVENTIS SLOVAKIA SRO	SK
Ibolex 200 mg filmom obalené tablety	AT/H/0112/001	29/0094/20-S	SANOFI-AVENTIS SLOVAKIA SRO	SK
Ibolex 200 mg filmom obalené tablety	AT/H/0112/001	29/0094/20-S	SANOFI-AVENTIS SLOVAKIA SRO	SK
Ibolex 200 mg potahované tablety	AT/H/0112/001	29/199/19-C	SANOFI-AVENTIS SRO	CZ
Ibolex 200 mg potahované tablety	AT/H/0112/001	29/199/19-C	SANOFI-AVENTIS SRO	CZ
Ibolex 200 mg potahované tablety	AT/H/0112/001	29/199/19-C	SANOFI-AVENTIS SRO	CZ
Ibolex 200 mg potahované tablety	AT/H/0112/001	29/199/19-C	SANOFI-AVENTIS SRO	CZ
Ibolex 200 mg potahované tablety	AT/H/0112/001	29/199/19-C	SANOFI-AVENTIS SRO	CZ
Ibolex 200 mg potahované tablety	AT/H/0112/001	29/199/19-C	SANOFI-AVENTIS SRO	CZ

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Ibolex 200 mg potahované tablety	AT/H/0112/001	29/199/19-C	SANOFI-AVENTIS SRO	CZ
Movone 200 mg - Filmtabletten	AT/H/0112/001	1-23573	GEBRO PHARMA GMBH	AT
Movone 300 mg - Filmtabletten	AT/H/0112/002	1-23574	GEBRO PHARMA GMBH	AT
Movone 400 mg - Filmtabletten	AT/H/0112/003	1-23575	GEBRO PHARMA GMBH	AT
Seractil 200 mg - Filmtabletten	not available	1-20001	GEBRO PHARMA GMBH	AT
SERACTIL 200 mg comprimate filmate	AT/H/0111/001	10251/2017/01	GALENICA SA	RO
SERACTIL 200 mg comprimate filmate	AT/H/0111/001	10251/2017/02	GALENICA SA	RO
SERACTIL 200 mg comprimate filmate	AT/H/0111/001	10251/2017/03	GALENICA SA	RO
SERACTIL 200 mg comprimate filmate	AT/H/0111/001	10251/2017/04	GALENICA SA	RO
SERACTIL 200 mg comprimate filmate	AT/H/0111/001	10251/2017/05	GALENICA SA	RO
SERACTIL 200 mg comprimate filmate	AT/H/0111/001	10251/2017/06	GALENICA SA	RO
SERACTIL 200 mg comprimate filmate	AT/H/0111/001	10251/2017/07	GALENICA SA	RO
Seractil 300 mg - Filmtabletten	not available	1-20002	GEBRO PHARMA GMBH	AT
Seractil 300 mg compresse rivestite con film	AT/H/0111/002	034765127	NEOPHARMED GENTILI SPA	IT
Seractil 300 mg compresse rivestite con film	AT/H/0111/002	034765089	NEOPHARMED GENTILI SPA	IT
Seractil 300 mg compresse rivestite con film	AT/H/0111/002	034765077	NEOPHARMED GENTILI 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
Seractil 300 mg compresse rivestite con film	AT/H/0111/002	034765091	NEOPHARMED GENTILI SPA	IT
Seractil 300 mg compresse rivestite con film	AT/H/0111/002	034765103	NEOPHARMED GENTILI SPA	IT
Seractil 300 mg compresse rivestite con film	AT/H/0111/002	034765115	NEOPHARMED GENTILI SPA	IT
SERACTIL 300 mg comprimate filmate	AT/H/0111/002	10252/2017/01	GALENICA SA	RO
SERACTIL 300 mg comprimate filmate	AT/H/0111/002	10252/2017/02	GALENICA SA	RO
SERACTIL 300 mg comprimate filmate	AT/H/0111/002	10252/2017/03	GALENICA SA	RO
SERACTIL 300 mg comprimate filmate	AT/H/0111/002	10252/2017/04	GALENICA SA	RO
SERACTIL 300 mg comprimate filmate	AT/H/0111/002	10252/2017/05	GALENICA SA	RO
SERACTIL 300 mg comprimate filmate	AT/H/0111/002	10252/2017/06	GALENICA SA	RO
SERACTIL 300 mg comprimate filmate	AT/H/0111/002	10252/2017/07	GALENICA SA	RO
SERACTIL 300 mg comprimate filmate	AT/H/0111/002	10252/2017/08	GALENICA SA	RO
SERACTIL 300 mg comprimate filmate	AT/H/0111/002	10252/2017/09	GALENICA SA	RO
Seractil 300 mg comprimidos revestidos por película	AT/H/0111/002	3920683	JABA RECORDATI, S.A.	PT
Seractil 300 mg comprimidos revestidos por película	AT/H/0111/002	3920584	JABA RECORDATI, S.A.	PT
Seractil 300 mg comprimidos revestidos	AT/H/0111/002	3333283	JABA RECORDATI, S.A.	PT

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
por película				
Seractil 300 mg comprimidos revestidos por película	AT/H/0111/002	3920782	JABA RECORDATI, S.A.	PT
Seractil 300 mg comprimidos revestidos por película	AT/H/0111/002	3920881	JABA RECORDATI, S.A.	PT
Seractil 300 mg comprimidos revestidos por película	AT/H/0111/002	3920980	JABA RECORDATI, S.A.	PT
Seractil 300 mg comprimidos revestidos por película	AT/H/0111/002	3921087	JABA RECORDATI, S.A.	PT
Seractil 300 mg comprimidos revestidos por película	AT/H/0111/002	4162681	JABA RECORDATI, S.A.	PT
Seractil 300 mg comprimidos revestidos por película	AT/H/0111/002	4162483	JABA RECORDATI, S.A.	PT
Seractil 300 mg comprimidos revestidos por película	AT/H/111/02	3333382	JABA RECORDATI, S.A.	PT
Seractil 300 mg polvere per sospensione orale	AT/H/0111/005	034765204	NEOPHARMED GENTILI SPA	IT
Seractil 300 mg επικαλυμμένα με λεπτό υμένιο δισκία	AT/H/0111/002	2489302	GALENICA SA	GR
Seractil 400 mg compresse rivestite con film	AT/H/0111/003	034765139	NEOPHARMED GENTILI SPA	IT
Seractil 400 mg compresse rivestite con film	AT/H/0111/003	034765141	NEOPHARMED GENTILI SPA	IT
Seractil 400 mg compresse rivestite con film	AT/H/0111/003	034765180	NEOPHARMED GENTILI 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
Seractil 400 mg compresse rivestite con film	AT/H/0111/003	034765166	NEOPHARMED GENTILI SPA	IT
Seractil 400 mg compresse rivestite con film	AT/H/0111/003	034765178	NEOPHARMED GENTILI SPA	IT
Seractil 400 mg compresse rivestite con film	AT/H/0111/003	034765154	NEOPHARMED GENTILI SPA	IT
SERACTIL 400 mg comprimate filmate	AT/H/0111/003	10253/2017/01	GALENICA SA	RO
SERACTIL 400 mg comprimate filmate	AT/H/0111/003	10253/2017/02	GALENICA SA	RO
SERACTIL 400 mg comprimate filmate	AT/H/0111/003	10253/2017/03	GALENICA SA	RO
SERACTIL 400 mg comprimate filmate	AT/H/0111/003	10253/2017/04	GALENICA SA	RO
SERACTIL 400 mg comprimate filmate	AT/H/0111/003	10253/2017/05	GALENICA SA	RO
SERACTIL 400 mg comprimate filmate	AT/H/0111/003	10253/2017/06	GALENICA SA	RO
SERACTIL 400 mg comprimate filmate	AT/H/0111/003	10253/2017/07	GALENICA SA	RO
SERACTIL 400 mg comprimate filmate	AT/H/0111/003	10253/2017/08	GALENICA SA	RO
SERACTIL 400 mg comprimate filmate	AT/H/0111/003	10253/2017/09	GALENICA SA	RO
SERACTIL 400 mg comprimate filmate	AT/H/0111/003	10253/2017/10	GALENICA SA	RO
SERACTIL 400 mg comprimidos recubiertos con película	AT/H/0111/003	63.574	LABORATORIOS GEBRO PHARMA, S.A.	ES
Seractil 400 mg comprimidos revestidos por película	AT/H/0111/003	4162780	JABA RECORDATI, S.A.	PT

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
Seractil 400 mg comprimidos revestidos por película	AT/H/0111/003	3921186	JABA RECORDATI, S.A.	PT
Seractil 400 mg comprimidos revestidos por película	AT/H/0111/003	3921285	JABA RECORDATI, S.A.	PT
Seractil 400 mg comprimidos revestidos por película	AT/H/0111/003	3921483	JABA RECORDATI, S.A.	PT
Seractil 400 mg comprimidos revestidos por película	AT/H/0111/003	3921681	JABA RECORDATI, S.A.	PT
Seractil 400 mg comprimidos revestidos por película	AT/H/0111/003	3921780	JABA RECORDATI, S.A.	PT
Seractil 400 mg comprimidos revestidos por película	AT/H/0111/003	3921384	JABA RECORDATI, S.A.	PT
Seractil 400 mg comprimidos revestidos por película	AT/H/0111/003	4162582	JABA RECORDATI, S.A.	PT
Seractil 400 mg comprimidos revestidos por película	AT/H/0111/003	3921582	JABA RECORDATI, S.A.	PT
Seractil 400 mg comprimidos revestidos por película	AT/H/111/03	3333481	JABA RECORDATI, S.A.	PT
Seractil 400 mg filmtabletta	not available	OGYI-T-7307/09	GEBRO PHARMA GMBH	HU
Seractil 400 mg filmtabletta	not available	OGYI-T-7307/10	GEBRO PHARMA GMBH	HU
Seractil 400 mg filmtabletta	not available	OGYI-T-7307/11	GEBRO PHARMA GMBH	HU
Seractil 400 mg filmtabletta	not available	OGYI-T-7307/12	GEBRO PHARMA GMBH	HU

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
Seractil 400 mg polvere per sospensione orale	AT/H/0111/006	034765279	NEOPHARMED GENTILI SPA	IT
Seractil 400 mg polvere per sospensione orale	AT/H/0111/006	034765216	NEOPHARMED GENTILI SPA	IT
Seractil 400 mg polvere per sospensione orale	AT/H/0111/006	034765228	NEOPHARMED GENTILI SPA	IT
Seractil 400 mg polvere per sospensione orale	AT/H/0111/006	034765230	NEOPHARMED GENTILI SPA	IT
Seractil 400 mg επικαλυμμένα με λεπτό υμένιο δισκία	AT/H/0111/003	2489303	GALENICA SA	GR
Seractil akut 300 mg Pulver zur Herstellung einer Suspension zum Einnehmen	AT/H/0111/005	1-27875	GEBRO PHARMA GMBH	AT
Seractil akut 400 mg Pulver zur Herstellung einer Suspension zum Einnehmen	AT/H/0111/006	1-27876	GEBRO PHARMA GMBH	AT
Seractil Dolo 200 mg filmtabletta	not available	OGYI-T-7307/01	GEBRO PHARMA GMBH	HU
Seractil Dolo 200 mg filmtabletta	not available	OGYI-T-7307/02	GEBRO PHARMA GMBH	HU
Seractil Dolo 200 mg filmtabletta	not available	OGYI-T-7307/03	GEBRO PHARMA GMBH	HU
Seractil Dolo 200 mg filmtabletta	not available	OGYI-T-7307/04	GEBRO PHARMA GMBH	HU
Seractil Dolo 300 mg filmtabletta	not available	OGYI-T-7307/05	GEBRO PHARMA GMBH	HU
Seractil Dolo 300 mg filmtabletta	not available	OGYI-T-7307/06	GEBRO PHARMA GMBH	HU
Seractil Dolo 300 mg filmtabletta	not available	OGYI-T-7307/07	GEBRO PHARMA GMBH	HU
Seractil Dolo 300 mg filmtabletta	not available	OGYI-T-7307/08	GEBRO PHARMA GMBH	HU

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
Seractil Dolo 300 mg filmtabletta	not available	OGYI-T-7307/13	GEBRO PHARMA GMBH	HU
Seractil forte 400 mg - Filmtabletten	not available	1-22547	GEBRO PHARMA GMBH	AT
Seractil, 200 mg, tabletki powlekane	not available	8441	BIOFARM SP. Z O.O.	PL
Seractil, 400 mg, tabletki powlekane	not available	8443	BIOFARM SP. Z O.O.	PL
Seractiv, filmovertrukne tabletter	AT/H/0111/003	31504	NORDIC DRUGS AB	DK
Seractiv, filmovertrukne tabletter	AT/H/0111/002	31503	NORDIC DRUGS AB	DK
Tradil 300 mg filmdragerad tablett	AT/H/0111/002	16317	NORDIC DRUGS AB	SE
Tradil 400 mg filmdragerad tablett	AT/H/0111/003	16318	NORDIC DRUGS AB	SE