



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 December 2023
EMA/37809/2024
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: piroxicam

Procedure no.: PSUSA/00002438/202304

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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
BREXIDOL 14 mg cerotto medicato	not available	038370019	PROMEDICA S.R.L.	IT
BREXIDOL 14 mg cerotto medicato	not available	038370021	PROMEDICA S.R.L.	IT
Brexidol 20 mg tabletter	not available	8013	CHIESI FARMACEUTICI S.P.A.	NO
Brexidol 20 mg tabletter	not available	11844	CHIESI FARMACEUTICI S.P.A.	SE
Brexidol 20 mg tabletter	not available	11844	CHIESI FARMACEUTICI S.P.A.	SE
BREXIN 20 mg compresse	not available	026446118	PROMEDICA S.R.L.	IT
BREXIN 20 mg compresse	not available	026446120	PROMEDICA S.R.L.	IT
BREXIN 20 mg compresse	not available	026446056	PROMEDICA S.R.L.	IT
BREXIN 20 mg compresse	not available	026446118	PROMEDICA S.R.L.	IT
BREXIN 20 mg compresse	not available	026446120	PROMEDICA S.R.L.	IT
BREXIN 20 mg compresse	not available	026446056	PROMEDICA S.R.L.	IT
BREXIN 20 mg compresse effervescenti	not available	026446132	PROMEDICA S.R.L.	IT
BREXIN 20 mg compresse effervescenti	not available	026446144	PROMEDICA S.R.L.	IT
BREXIN 20 mg compresse effervescenti	not available	026446157	PROMEDICA S.R.L.	IT
BREXIN 20 mg compresse effervescenti	not available	026446169	PROMEDICA S.R.L.	IT
BREXIN 20 mg granulato per soluzione orale	not available	026446031	PROMEDICA S.R.L.	IT
Brexin 20 mg milteljai geriamajam tirpalui	not available	LT/1/2000/1566/002	CHIESI PHARMACEUTICALS GMBH	LT
Brexin 20 mg tablettes	not available	LT/1/2000/1566/001	CHIESI PHARMACEUTICALS GMBH	LT
Brexin 20 mg tablettes	not available	03-0566	CHIESI PHARMACEUTICALS GMBH	LV
Brexin 20 mg tabletta	not available	OGYI-T-8393/02	CHIESI PHARMACEUTICALS GMBH	HU
Brexin 20 mg tabletta	not available	OGYI-T-8393/01	CHIESI PHARMACEUTICALS GMBH	HU

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Brexin 20 mg tabletta	not available	OGYI-T-8393/04	CHIESI PHARMACEUTICALS GMBH	HU
Brexin 20 mg tabletta	not available	OGYI-T-8393/03	CHIESI PHARMACEUTICALS GMBH	HU
Brexin 20 mg tabletta	not available	OGYI-T-8393/02	CHIESI PHARMACEUTICALS GMBH	HU
Brexin 20 mg tabletta	not available	OGYI-T-8393/01	CHIESI PHARMACEUTICALS GMBH	HU
Brexin 20 mg tabletta	not available	OGYI-T-8393/04	CHIESI PHARMACEUTICALS GMBH	HU
Brexin 20 mg tabletta	not available	OGYI-T-8393/03	CHIESI PHARMACEUTICALS GMBH	HU
BREXIN 20 mg, comprimé effervescent	not available	34009 348 777 0 4	PIERRE FABRE MEDICAMENT	FR
BREXIN 20 mg, comprimé effervescent	not available	34009 348 778 7 2	PIERRE FABRE MEDICAMENT	FR
BREXIN 20 mg, comprimé effervescent	not available	34009 348 779 3 3	PIERRE FABRE MEDICAMENT	FR
BREXIN 20 mg, comprimé effervescent	not available	34009 348 780 1 5	PIERRE FABRE MEDICAMENT	FR
BREXIN 20 mg, comprimé sécable	not available	34009 335 411 2 5	PIERRE FABRE MEDICAMENT	FR
BREXIN 20 mg, comprimé sécable	not available	34009 335 959 8 2	PIERRE FABRE MEDICAMENT	FR
BREXIN, 20 mg tabletid	not available	313800	CHIESI PHARMACEUTICALS GMBH	EE
BREXIN® 20 mg tablets	not available	14762	CHIESI HELLAS S.A.	CY
BREXIN® 20 mg, δισκία.	not available	2054202	CHIESI HELLAS S.A.	GR
BREXIN® 20 mg, κοκκία μιας δόσης για πόσιμο υγρό σε φακελάκις.	not available	2054201	CHIESI HELLAS S.A.	GR
BREXIN® Dref 20 mg, αναβράζοντα δισκία	not available	2054203	CHIESI HELLAS S.A.	GR
BREXINE 20 mg TABLETTEN	not available	BE157586	CHIESI SA/NV	BE
BREXINE® 20 mg	not available	BE157586	CHIESI SA/NV	BE

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COMPRIMÉS				
BREXINE® 20 mg COMPRIMÉS	not available	2010080830 0177662	CHIESI SA/NV	LU
BREXINE® 20 mg COMPRIMÉS	not available	2010080830 0177676	CHIESI SA/NV	LU
BREXINE® 20 mg COMPRIMÉS	not available	2010080830 0224651	CHIESI SA/NV	LU
BREXINE® 20 mg TABLETTEN	not available	BE157586	CHIESI SA/NV	BE
BREXINE®-DRYFIZ® 20 mg BRAUSETABLETTEN	not available	BE161296	CHIESI SA/NV	BE
BREXINE®-DRYFIZ® 20 mg BRAUSETABLETTEN	not available	BE161296	CHIESI SA/NV	BE
BREXINE®-DRYFIZ® 20 mg COMPRIMÉS EFFERVESCENTS	not available	BE161296	CHIESI SA/NV	BE
BREXINE®-DRYFIZ® 20 mg COMPRIMÉS EFFERVESCENTS	not available	BE161296	CHIESI SA/NV	BE
BREXINE®-DRYFIZ® 20 mg COMPRIMÉS EFFERVESCENTS	not available	2010080832	CHIESI SA/NV	LU
BREXINE®-DRYFIZ® 20 mg COMPRIMÉS EFFERVESCENTS	not available	2010080832	CHIESI SA/NV	LU
BREXINE®-DRYFIZ® 20 mg COMPRIMÉS EFFERVESCENTS	not available	2010080832	CHIESI SA/NV	LU
BREXINE®-DRYFIZ® 20 mg COMPRIMÉS EFFERVESCENTS	not available	2010080832 0279886	CHIESI SA/NV	LU
BREXINE®-DRYFIZ® 20 mg COMPRIMÉS EFFERVESCENTS	not available	2010080832	CHIESI SA/NV	LU
BREXINE-DRYFIZ 20 mg BRUISTABLETTEN	not available	BE161296	CHIESI SA/NV	BE

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BREXINE-DRYFIZ 20 mg BRUISTABLETTEN	not available	BE161296	CHIESI SA/NV	BE
CICLADOL 20 mg comprimé	not available	026447110	MASTER PHARMA S.R.L.	IT
CICLADOL 20 mg comprimé	not available	026447122	MASTER PHARMA S.R.L.	IT
CICLADOL 20 mg comprimé	not available	026447058	MASTER PHARMA S.R.L.	IT
CICLADOL 20 mg comprimé effervescent	not available	026447134	MASTER PHARMA S.R.L.	IT
CICLADOL 20 mg comprimé effervescent	not available	026447146	MASTER PHARMA S.R.L.	IT
CICLADOL 20 mg comprimé effervescent	not available	026447159	MASTER PHARMA S.R.L.	IT
CICLADOL 20 mg comprimé effervescent	not available	026447161	MASTER PHARMA S.R.L.	IT
CICLADOL 20 mg granulato per soluzione orale	not available	026447033	MASTER PHARMA S.R.L.	IT
CYCLADOL 20 mg, comprimé effervescent	not available	3400934877353	CHIESI S.A.S.	FR
CYCLADOL 20 mg, comprimé effervescent	not available	3400934877414	CHIESI S.A.S.	FR
CYCLADOL 20 mg, comprimé effervescent	not available	3400934877582	CHIESI S.A.S.	FR
CYCLADOL 20 mg, comprimé effervescent	not available	3400934877643	CHIESI S.A.S.	FR
CYCLADOL 20 mg, comprimé sécable	not available	34009 336 095 7 3	CHIESI S.A.S.	FR
CYCLADOL 20 mg, comprimé sécable	not available	34009 336 094 0 5	CHIESI S.A.S.	FR
CYCLADOL 20 mg, comprimé sécable	not available	34009 336 093 4 4	CHIESI S.A.S.	FR
CYCLADOL 20 mg, comprimé sécable	not available	34009 336 092 8 3	CHIESI S.A.S.	FR
Feldegel 5 mg/g gel	not available	57.797	PFIZER, S.L.	ES

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
Felden 0,5 % gel	not available	10158	PFIZER OY	FI
FELDEN 0,5% - Gel	not available	1-18971	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
Felden 0,5% hlaup.	not available	930143	PFIZER APS	IS
Felden, gel	not available	12337	PFIZER APS	DK
FELDEN® 10 mg – Kapseln	not available	16.690	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
FELDEN® 20 mg – Ampullen	not available	1-18967	PFIZER CORPORATION AUSTRIA GES.M.B.H.	AT
FELDEN® 20 mg – Kapseln	not available	17.048	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
FELDEN® 20 mg – Tabletten zur Herstellung einer Suspension zum Einnehmen	not available	1-18280	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
FELDEN® Quick-Solve 20 mg – Schmelztabletten	not available	1-20748	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
Feldene 0.5% w/w Gel.	not available	PL 00057/0284	PFIZER LIMITED	XI
FELDENE 10 mg cápsulas duras	not available	55.382	PFIZER S.L.	ES
Feldene 10 mg διασπειρόμενα δισκία	not available	41095/10/31-05-2011	PFIZER HELLAS, A.E.	GR
FELDENE 10 mg, gélule	not available	34009 324 221 2 8	PFIZER HOLDING FRANCE	FR
FELDENE 10mg CAPSULES	not available	PL 00057/0145	PFIZER LIMITED	XI
FELDENE 20 mg cápsulas duras	not available	55.806	PFIZER S.L.	ES
FELDENE 20 mg capsule rigide	not available	024249029	PFIZER ITALIA S.R.L.	IT
FELDENE 20 mg compresse solubili	not available	024249056	PFIZER ITALIA S.R.L.	IT
FELDENE 20 mg supposte	not available	024249031	PFIZER ITALIA S.R.L.	IT
Feldene 20 mg	not available	12074	PFIZER HELLAS, A.E.	CY

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διασπειρόμενα δισκία				
Feldene 20 mg διασπειρόμενα δισκία	not available	41097/10/31-05-2011	PFIZER HELLAS, A.E.	GR
FELDENE 20 mg, gélule	not available	34009 326 369 7 6	PFIZER HOLDING FRANCE	FR
FELDENE 20 mg, gélule	not available	34009 326 679 6 3	PFIZER HOLDING FRANCE	FR
FELDENE 20 mg, suppositoire	not available	34009 326 680 4 5	PFIZER HOLDING FRANCE	FR
FELDENE 20 mg, suppositoire	not available	34009 326 382 3 9	PFIZER HOLDING FRANCE	FR
Feldene 20 mg/1 ml solução injetável	not available	5378021	LABORATÓRIOS PFIZER LDA.	PT
Feldene 20 mg/1 ml solução injetável	not available	8675405	LABORATÓRIOS PFIZER LDA.	PT
FELDENE 20 mg/1 ml soluzione iniettabile per uso intramuscolare	not available	024249068	PFIZER ITALIA S.R.L.	IT
FELDENE 20 mg/1 ml, solution injectable en ampoule (IM)	not available	34009 328 610 3 3	PFIZER HOLDING FRANCE	FR
FELDENE 20 mg/1 ml, solution injectable en ampoule (IM)	not available	34009 328 609 5 1	PFIZER HOLDING FRANCE	FR
FELDENE 20 mg/ml solución inyectable	not available	58.085	PFIZER S.L.	ES
FELDENE 20mg CAPSULES	not available	PL 00057/0146	PFIZER LIMITED	XI
Feldene 5 mg/g Gel	not available	PA 0822/194/003	PFIZER HEALTHCARE IRELAND	IE
Feldene 5 mg/g gel	not available	8675512	LABORATÓRIOS PFIZER, LDA.	PT
FELDENE CREMADOL 1% crema	not available	035443011	PFIZER ITALIA S.R.L.	IT
Feldene Dispersal 20 mg diszpergálódó tabletta	not available	OGYI-T-1141/05	PFIZER KFT.	HU
Feldene Dispersal 20 mg diszpergálódó tabletta	not available	OGYI-T-1141/07	PFIZER KFT.	HU
Feldene Dispersal 20 mg	not available	OGYI-T-1141/06	PFIZER KFT.	HU

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diszpergálódó tabletta				
Feldene Dispersal 20 mg diszpergálódó tabletta	not available	OGYI-T-1141/08	PFIZER KFT.	HU
FELDENE DISPERSIBLE 20 mg, comprimé dispersible sécable	not available	34009 331 938 6 7	PFIZER HOLDING FRANCE	FR
FELDENE DISPERSIBLE 20 mg, comprimé dispersible sécable	not available	34009 331 936 3 8	PFIZER HOLDING FRANCE	FR
FELDENE DISPERSIBLE 20 mg, comprimé dispersible sécable	not available	34009 331 939 2 8	PFIZER HOLDING FRANCE	FR
FELDENE DISPERSIBLE 20 mg, comprimé dispersible sécable	not available	34009 342 241 1 9	PFIZER HOLDING FRANCE	FR
FELDENE Fast 20 mg compresse sublinguali	not available	028437034	PFIZER ITALIA S.R.L.	IT
FELDENE Fast 20 mg compresse sublinguali	not available	028437022	PFIZER ITALIA S.R.L.	IT
FELDENE FLAS 20 mg liofilizado oral	not available	60.070	PFIZER S.L.	ES
Feldene Melt 20mg.	not available	PL 00057/0352	PFIZER LIMITED	XI
FELDENE, roztwór do wstrzykiwań, 20 mg/ml	not available	R/2346	PFIZER EUROPE MA EEIG	PL
FLAMEXIN 20 mg tablety	not available	29/116/96-C	CHIESI FARMACEUTICI S.P.A.	CZ
FLAMEXIN 20 mg tablety	not available	29/116/96-C	CHIESI FARMACEUTICI S.P.A.	CZ
Flamexin 20 mg tablety	not available	29/0114/99-S	CHIESI FARMACEUTICI S.P.A.	SK
Flamexin 20 mg tablety	not available	29/0114/99-S	CHIESI FARMACEUTICI S.P.A.	SK
Flamexin, 20 mg, comprimate	not available	7146/2006/01	CHIESI FARMACEUTICI S.P.A.	RO
Flamexin, 20 mg, comprimate	not available	7146/2006/02	CHIESI FARMACEUTICI S.P.A.	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
Flamexin, 20 mg, comprimate	not available	7146/2006/03	CHIESI FARMACEUTICI S.P.A.	RO
Flamexin, 20 mg, comprimate	not available	7146/2006/01	CHIESI FARMACEUTICI S.P.A.	RO
Flamexin, 20 mg, comprimate	not available	7146/2006/02	CHIESI FARMACEUTICI S.P.A.	RO
Flamexin, 20 mg, comprimate	not available	7146/2006/03	CHIESI FARMACEUTICI S.P.A.	RO
Flamexin, 20 mg, pulbere pentru soluție orală	not available	7597/2006/01	CHIESI FARMACEUTICI S.P.A.	RO
Flamexin, 20 mg, pulbere pentru soluție orală	not available	7597/2006/02	CHIESI FARMACEUTICI S.P.A.	RO
Flamexin, 20 mg, pulbere pentru soluție orală	not available	7597/2006/03	CHIESI FARMACEUTICI S.P.A.	RO
Flamexin, 20 mg, pulbere pentru soluție orală	not available	7597/2006/04	CHIESI FARMACEUTICI S.P.A.	RO
Flamexin, 20 mg, pulbere pentru soluție orală	not available	7597/2006/05	CHIESI FARMACEUTICI S.P.A.	RO
Flamexin, 20 mg, pulbere pentru soluție orală	not available	7597/2006/06	CHIESI FARMACEUTICI S.P.A.	RO
Flamexin, 20 mg, pulbere pentru soluție orală	not available	7597/2006/01	CHIESI FARMACEUTICI S.P.A.	RO
Flamexin, 20 mg, pulbere pentru soluție orală	not available	7597/2006/02	CHIESI FARMACEUTICI S.P.A.	RO
Flamexin, 20 mg, pulbere pentru soluție orală	not available	7597/2006/03	CHIESI FARMACEUTICI S.P.A.	RO
Flamexin, 20 mg, pulbere pentru soluție orală	not available	7597/2006/04	CHIESI FARMACEUTICI S.P.A.	RO
Flamexin, 20 mg, pulbere pentru soluție orală	not available	7597/2006/05	CHIESI FARMACEUTICI S.P.A.	RO
Flamexin, 20 mg, pulbere pentru soluție orală	not available	7597/2006/06	CHIESI FARMACEUTICI S.P.A.	RO
Flamexin, 20 mg, tabletki	not available	9222	CHIESI FARMACEUTICI S.P.A.	PL
Flamexin, 20 mg, tabletki	not available	9222	CHIESI FARMACEUTICI S.P.A.	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
FLECTOR UNIDIE 14 mg cerotto medicato	not available	038354027	IBSA FARMACEUTICI ITALIA	IT
FLECTOR UNIDIE 14 mg cerotto medicato	not available	038354015	IBSA FARMACEUTICI ITALIA	IT
Flexar 20 mg cápsulas	not available	4679593	A. MENARINI PORTUGAL, FARMACÊUTICA, S.A.	PT
Flexar 20 mg cápsulas	not available	4614996	A. MENARINI PORTUGAL, FARMACÊUTICA, S.A.	PT
Flexar 20 mg cápsulas	not available	5878491	A. MENARINI PORTUGAL, FARMACÊUTICA, S.A.	PT
Flexar 20 mg cápsulas	not available	5878590	A. MENARINI PORTUGAL, FARMACÊUTICA, S.A.	PT
Flexar 20 mg supositórios	not available	9702902	A. MENARINI PORTUGAL, FARMACÊUTICA, S.A.	PT
Flexar 20 mg/1 ml solução injetável	not available	2065894	A. MENARINI PORTUGAL, FARMACÊUTICA, S.A.	PT
Flexar 5 mg/g gel	not available	2583599	A. MENARINI PORTUGAL, FARMACÊUTICA, S.A.	PT
GELDENE 0,5 POUR CENT, gel pour application locale	not available	34009 331 669 5 3	PFIZER HOLDING FRANCE	FR
GELDENE 0,5 POUR CENT, gel pour application locale	not available	34009 331 670 3 5	PFIZER HOLDING FRANCE	FR
IMPRONTAL 5 mg/g Crema	not available	58.198	MEDA PHARMA S.L.	ES
LENOSPREAD CREMA Piroxicam	not available	025496062	I.B.N. SAVIO S.R.L.	IT
LENOTAC 14 mg cerotto medicato	not available	038356022	I.B.N. SAVIO S.R.L.	IT
LENOTAC 14 mg cerotto medicato	not available	038356010	I.B.N. SAVIO S.R.L.	IT
PIROFTAL 0.5% collirio soluzione	not available	025986011	BRUSCHETTINI S.R.L	IT
Piroxicam 0.5% Gel	not available	PL 20075/0704	ACCORD HEALTHCARE LIMITED	XI
Piroxicam 0.5% w/w Gel	not available	PL 36687/0344	TORRENT PHARMA (UK) LTD.	XI
Piroxicam Capsules 10mg	not available	PL 20416/0137	CRESCENT PHARMA	XI

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			LIMITED	
Piroxicam Capsules 20mg	not available	PL 20416/0138	CRESCENT PHARMA LIMITED	XI
Piroxicam EG 20 mg capsules	not available	BE167054	EUROGENERICS N.V./S.A.	BE
Piroxicam EG 20 mg comprimés dispersibles	not available	BE167115	EUROGENERICS N.V./S.A.	BE
Piroxicam EG 20 mg comprimés dispersibles	not available	BE167115	EUROGENERICS N.V./S.A.	BE
Piroxicam EG 20 mg comprimés dispersibles	not available	2007060016	EUROGENERICS N.V./S.A.	LU
Piroxicam EG 20 mg dispergeerbare tabletten	not available	BE167115	EUROGENERICS N.V./S.A.	BE
Piroxicam EG 20 mg gélules	not available	BE167054	EUROGENERICS N.V./S.A.	BE
Piroxicam EG 20 mg gélules	not available	2007060014	EUROGENERICS N.V./S.A.	LU
Piroxicam EG 20 mg Kapseln	not available	BE167054	EUROGENERICS N.V./S.A.	BE
Piroxicam EG 20 mg Tabletten zur Herstellung einer Suspension zum Einnehmen	not available	BE167115	EUROGENERICS N.V./S.A.	BE
Piroxicam EG 20 mg/ml Injektionslösung	not available	BE228076	EUROGENERICS N.V./S.A.	BE
Piroxicam EG 20 mg/ml oplossing voor injectie	not available	BE228076	EUROGENERICS N.V./S.A.	BE
Piroxicam EG 20 mg/ml solution injectable	not available	2007060015	EUROGENERICS N.V./S.A.	LU
Piroxicam Manx 0.5%w/w Gel	not available	PL 14251/0028	MANX HEALTHCARE LTD	XI
PIROXICAM VIATRIS 20 mg, comprimé dispersible sécable	not available	NL 23555	VIATRIS SANTE	FR
PIROXICAM VIATRIS 20 mg, gélule	not available	NL 21220	VIATRIS SANTE	FR

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
Relivate Aches and Joint Pain Relief 0.5%w/w Gel	not available	PL 14251/0028	MANX HEALTHCARE LTD	XI
Salvacam 5 mg/g Gel	not available	58.986	LABORATORIOS SALVAT, S.A.	ES
SASULEN 5 mg/g gel	not available	58.708	LABORATORIOS VERIS, S.A.	ES
Trifenactif 10 mg/g Creme	not available	5795620	MEDINFAR CONSUMER HEALTH - PRODUTOS FARMACÊUTICOS,LDA	PT
ФЛАМЕКСИН 20 mg прах за перорален разтвор	not available	20000197	CHIESI PHARMACEUTICALS GMBH	BG
ФЛАМЕКСИН 20 mg таблетки	not available	20000196	CHIESI PHARMACEUTICALS GMBH	BG