



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

08 February 2024
EMA/156960/2024
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: diclofenac / misoprostol

Procedure no.: PSUSA/00001040/202307

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union



Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number (if not available then insert not available)	National Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
Arthrotec® forte Manteltabletten	not available	1-22960	PFIZER CORPORATION AUSTRIA GES.M.B.H.	AT
Arthrotec® Manteltabletten	not available	1-22959	PFIZER CORPORATION AUSTRIA GES.M.B.H.	AT
Arthrotec 75, Tabletten mit veränderter Wirkstofffreisetzung	FI/H/1029/001	BE182847	PFIZER S.A.	BE
Arthrotec® forte Manteltabletten mit 75 mg Diclofenac-Natrium und 0,2 mg Misoprostol	not available	40421.00.00	PFIZER PHARMA GMBH	DE
Arthrotec Forte, tabletter med modificeret udløsning	not available	18455	PFIZER APS	DK
Arthrotec, tabletter med modificeret udløsning	not available	15278	PFIZER APS	DK

Artrotec 50 mg /200 microgramos comprimidos recubiertos	not available	61.079	PFIZER S.L.	ES
Arthrotec 50 mg / 0,2 mg säädellysti vapauttavat tabletit	not available	11571	PFIZER OY	FI
Arthrotec Forte säädellysti vapauttavat tabletit	FI/H/1029/001	12480	PFIZER OY	FI
Arthrotec 50 modified-release tablets	not available	PA 0822/112/001	PFIZER HEALTHCARE IRELAND	IE
Arthrotec 75 modified-release tablets	FI/H/1029/001	PA 0822/112/002	PFIZER HEALTHCARE IRELAND	IE
Arthrotec	not available	910006	PFIZER APS	IS
Arthrotec Forte	not available	IS/1/09/104/01	PFIZER APS	IS

ARTROTEC 50 mg + 200 mcg compresse	not available	029757034	PFIZER ITALIA S.R.L.	IT
ARTROTEC 50 mg + 200 mcg compresse	not available	029757022	PFIZER ITALIA S.R.L.	IT
ARTROTEC 50 mg + 200 mcg compresse	not available	029757010	PFIZER ITALIA S.R.L.	IT
Artrotec 75 compresse a rilascio modificato	FI/H/1029/001	029757046	PFIZER ITALIA S.R.L.	IT
Artrotec 75 compresse a rilascio modificato	FI/H/1029/001	029757059	PFIZER ITALIA S.R.L.	IT
MISOFENAC 50 mg + 200 mcg compresse	not available	029316039	PFIZER ITALIA S.R.L.	IT
MISOFENAC 50 mg + 200 mcg compresse	not available	029316015	PFIZER ITALIA S.R.L.	IT

MISOFENAC 50 mg + 200 mcg comprese	not available	029316027	PFIZER ITALIA S.R.L.	IT
Misofenac 75 compresse a rilascio modificato	FI/H/1029/001	029316041	PFIZER ITALIA S.R.L.	IT
Misofenac 75 compresse a rilascio modificato	FI/H/1029/001	029316054	PFIZER ITALIA S.R.L.	IT
Arthrotec 75 comprimés à libération modifiée	FI/H/1029/001	2009050435	PFIZER S.A. (BELGIUM)	LU
Arthrotec 50, tabletten met gereguleerde afgifte	not available	RVG 16410	PFIZER B.V.	NL
Arthrotec 75, tabletten met gereguleerde afgifte	FI/H/1029/001	RVG 20871	PFIZER B.V.	NL
Arthrotec 50 mg/0,2 mg tabletter med modifisert frisetting	not available	00-8123	PFIZER AS	NO

ARTHROTEC Forte, 75 mg + 0,2 mg, tabletki	not available	4221	PFIZER EUROPE MA EEIG	PL
ARTHROTEC, 50 mg + 0,2 mg, tabletki	not available	7964	PFIZER EUROPE MA EEIG	PL
Arthrotec 50 mg + 0,2 mg comprimidos	not available	4632881	LABORATÓRIOS PFIZER, LDA.	PT
Arthrotec 50 mg + 0,2 mg comprimidos	not available	8786210	LABORATÓRIOS PFIZER, LDA.	PT
Arthrotec 50 mg + 0,2 mg comprimidos	not available	8786202	LABORATÓRIOS PFIZER, LDA.	PT
Arthrotec 50 mg + 0,2 mg comprimidos	not available	4632782	LABORATÓRIOS PFIZER, LDA.	PT
Arthrotec 75, 75 mg + 0,2 mg, comprimidos de libertação modificada	FI/H/1029/001	2536084	LABORATÓRIOS PFIZER, LDA.	PT

Arthrotec 75, 75 mg + 0,2 mg, comprimidos de libertação modificada	FI/H/1029/001	2536183	LABORATÓRIOS PFIZER, LDA.	PT
Arthrotec 75, 75 mg + 0,2 mg, comprimidos de libertação modificada	FI/H/1029/001	4029385	LABORATÓRIOS PFIZER, LDA.	PT
Arthrotec 75, 75 mg + 0,2 mg, comprimidos de libertação modificada	FI/H/1029/001	4028981	LABORATÓRIOS PFIZER, LDA.	PT
Arthrotec 75, 75 mg + 0,2 mg, comprimidos de libertação modificada	FI/H/1029/001	4029088	LABORATÓRIOS PFIZER, LDA.	PT
Arthrotec 75, 75 mg + 0,2 mg, comprimidos de libertação modificada	FI/H/1029/001	4029286	LABORATÓRIOS PFIZER, LDA.	PT
Arthrotec 75, 75 mg + 0,2 mg, comprimidos de libertação modificada	FI/H/1029/001	4029187	LABORATÓRIOS PFIZER, LDA.	PT
ARTHROTEC 75 mg/0,2 mg comprimato gastroresistente	not available	12398/2019/02	PFIZER EUROPE MA EEIG	RO

ARTHROTEC 75 mg/0,2 mg comprimata gastroresistente	not available	12398/2019/01	PFIZER EUROPE MA EEIG	RO
Arthrotec 50 mg/0,2 mg, tabletter med modifierad frisättning	not available	11657	PFIZER AB	SE
Arthrotec Forte 75 mg/0,2 mg, tabletter med modifierad frisättning	FI/H/1029/001	13276	PFIZER AB	SE
ARTHROTEC FORTE 75 mg/0,2 mg filmom obalené tablety	not available	29/0199/95-S	PFIZER EUROPE MA EEIG	SK
Arthrotec 50 modified-release tablets.	not available	PL 00057/0931	PFIZER LIMITED	XI
Arthrotec 75 modified-release tablets	FI/H/1029/001	PL 00057/0932	PFIZER LIMITED	XI