12 March 2026
EMADOC-1700519818-2996711
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): diclofenac / misoprostol

EURD list No. PSUSA/00001040/202507

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 Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	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® forte Manteltabletten	not available	1-22960	PFIZER CORPORATION AUSTRIA GES.M.B.H.	AT
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® Manteltabletten	not available	1-22959	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 met gereguleerde afgifte.	FI/H/1029/001	BE182847	PFIZER S.A.	BE
Arthotec® forte Manteltabletten mit 75 mg Diclofenac-Natrium und 0,2 mg Misoprostol	not available	40421.00.00	PFIZER PHARMA GMBH	DE
Arthotec® forte Manteltabletten mit 75 mg Diclofenac-Natrium und 0,2 mg Misoprostol	not available	40421.00.00	PFIZER PHARMA GMBH	DE
Arthotec® forte Manteltabletten mit 75 mg Diclofenac-Natrium und 0,2 mg Misoprostol	not available	40421.00.00	PFIZER PHARMA GMBH	DE
Artrotec 50 mg /200 microgramos comprimidos recubiertos	not available	61.079	PFIZER S.L.	ES
Arthrotec Forte säädellysti vapauttavat tabletit	FI/H/1029/001	12480	PFIZER OY	FI

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
Arthrotec 50 modified-release tablets	not available	PA 0822/112/001	PFIZER HEALTHCARE IRELAND UNLIMITED COMPANY	IE
Arthrotec 50 modified-release tablets	not available	PA 0822/112/001	PFIZER HEALTHCARE IRELAND UNLIMITED COMPANY	IE
Arthrotec 50 modified-release tablets	not available	PA 0822/112/001	PFIZER HEALTHCARE IRELAND UNLIMITED COMPANY	IE
Arthrotec 50 modified-release tablets	not available	PA 0822/112/001	PFIZER HEALTHCARE IRELAND UNLIMITED COMPANY	IE
Arthrotec 50 modified-release tablets	not available	PA 0822/112/001	PFIZER HEALTHCARE IRELAND UNLIMITED COMPANY	IE
Arthrotec 50 modified-release tablets	not available	PA 0822/112/001	PFIZER HEALTHCARE IRELAND UNLIMITED COMPANY	IE
Arthrotec 75 modified-release tablets	FI/H/1029/001	PA 0822/112/002	PFIZER HEALTHCARE IRELAND UNLIMITED COMPANY	IE
Arthrotec 75 modified-release tablets	FI/H/1029/001	PA 0822/112/002	PFIZER HEALTHCARE IRELAND UNLIMITED COMPANY	IE
Arthrotec 75 modified-release tablets	FI/H/1029/001	PA 0822/112/002	PFIZER HEALTHCARE IRELAND UNLIMITED COMPANY	IE
Arthrotec 75 modified-release tablets	FI/H/1029/001	PA 0822/112/002	PFIZER HEALTHCARE IRELAND UNLIMITED COMPANY	IE
Arthrotec 75 modified-release tablets	FI/H/1029/001	PA 0822/112/002	PFIZER HEALTHCARE IRELAND UNLIMITED COMPANY	IE

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
Arthrotec 75 modified-release tablets	FI/H/1029/001	PA 0822/112/002	PFIZER HEALTHCARE IRELAND UNLIMITED COMPANY	IE
Arthrotec 75 modified-release tablets	FI/H/1029/001	PA 0822/112/002	PFIZER HEALTHCARE IRELAND UNLIMITED COMPANY	IE
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 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.	LU
Arthrotec 50, tabletten met gereguleerde afgifte	not available	RVG 16410	PFIZER B.V.	NL
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

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Arthrotec 75, tabletten met gereguleerde afgifte	FI/H/1029/001	RVG 20871	PFIZER B.V.	NL
Arthrotec 75, tabletten met gereguleerde afgifte	FI/H/1029/001	RVG 20871	PFIZER B.V.	NL
Arthrotec 75, tabletten met gereguleerde afgifte	FI/H/1029/001	RVG 20871	PFIZER B.V.	NL
Arthrotec 75, tabletten met gereguleerde afgifte	FI/H/1029/001	RVG 20871	PFIZER B.V.	NL
Arthrotec 75, tabletten met gereguleerde afgifte	FI/H/1029/001	RVG 20871	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 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 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, tabletki	not available	7964	PFIZER EUROPE MA EEIG	PL
ARTHROTEC, 50 mg + 0,2 mg, tabletki	not available	7964	PFIZER EUROPE MA EEIG	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
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 comprimate gastrorezistente	not available	12398/2019/02	PFIZER EUROPE MA EEIG	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
ARTHROTEC 75 mg/0,2 mg comprimate gastrorezistente	not available	12398/2019/01	PFIZER EUROPE MA EEIG	RO
ARTHROTEC FORTE 75 mg/0,2 mg filmom obalené tablety	not available	29/0199/95-S	PFIZER EUROPE MA EEIG	SK
ARTHROTEC FORTE 75 mg/0,2 mg filmom obalené tablety	not available	29/0199/95-S	PFIZER EUROPE MA EEIG	SK
ARTHROTEC FORTE 75 mg/0,2 mg filmom obalené tablety	not available	29/0199/95-S	PFIZER EUROPE MA EEIG	SK
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 50 modified-release tablets.	not available	PL 00057/0931	PFIZER LIMITED	XI
Arthrotec 50 modified-release tablets.	not available	PL 00057/0931	PFIZER LIMITED	XI
Arthrotec 50 modified-release tablets.	not available	PL 00057/0931	PFIZER LIMITED	XI
Arthrotec 50 modified-release tablets.	not available	PL 00057/0931	PFIZER LIMITED	XI
Arthrotec 50 modified-release tablets.	not available	PL 00057/0931	PFIZER LIMITED	XI
Arthrotec 50 modified-release tablets.	not available	PL 00057/0931	PFIZER LIMITED	XI
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
Arthrotec 75 modified-release tablets	FI/H/1029/001	PL 00057/0932	PFIZER LIMITED	XI

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Arthrotec 75 modified-release tablets	FI/H/1029/001	PL 00057/0932	PFIZER LIMITED	XI
Arthrotec 75 modified-release tablets	FI/H/1029/001	PL 00057/0932	PFIZER LIMITED	XI
Arthrotec 75 modified-release tablets	FI/H/1029/001	PL 00057/0932	PFIZER LIMITED	XI
Arthrotec 75 modified-release tablets	FI/H/1029/001	PL 00057/0932	PFIZER LIMITED	XI
Arthrotec 75 modified-release tablets	FI/H/1029/001	PL 00057/0932	PFIZER LIMITED	XI