



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 March 2018
EMA/265069/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: diclofenac / misoprostol

Procedure no.: PSUSA/00001040/201707



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	UK/H/0136/001	PA 0822/112/002	PFIZER HEALTHCARE IRELAND	IE
Arthrotec 50 modified-release tablets	not available	PA 0822/112/001	PFIZER HEALTHCARE IRELAND	IE
Arthrotec Forte, tabletter med modifierad frisättning	UK/H/0136/001	12480	PFIZER OY	FI
Arthrotec 50 mg/0,2 mg tabletter diklofenaknatrium/misoprostol	not available	11571	PFIZER OY	FI
Arthrotec® 75, Tabletten mit veränderter Wirkstofffreisetzung	UK/H/0136/001	BE182847	CONTINENTAL PHARMA, INC.	BE
Arthrotec 75 comprimés à libération modifiée	UK/H/0136/001	BE182847	CONTINENTAL PHARMA, INC.	BE
Arthrotec 75 tabletten met gereguleerde afgifte	UK/H/0136/001	BE182847	CONTINENTAL PHARMA, INC.	BE
Arthrotec töflur	not available	910006	PFIZER APS	IS
ARTHROTEC 75 mg/ 0,2 mg comprimate gastrorezistente	not available	5640/2005/01	PFIZER EUROPE MA EEIG	RO
Arthrotec Forte töflur	not available	IS/1/09/104/01	PFIZER APS	IS
Arthrotec 50 mg/0,2 mg tabletti	not available	11571	PFIZER OY	FI
Arthrotec® forte Manteltabletten	not available	1-22960	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
Arthrotec® Manteltabletten	not available	1-22959	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
Arthrotec, tabletter	not available	15278	PFIZER APS	DK

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Arthrotec 50 mg/0,2 mg tabletter med modificert frisetting	not available	00-8123	PFIZER AS	NO
ARTROTEC 50 mg + 200 mcg comprime	not available	029757034	PFIZER ITALIA S.R.L.	IT
ARTHROTEC FORTE 75 mg/200 µg filmom obalené tablety	not available	29/0199/95-S	PFIZER EUROPE MA EEIG	SK
MISOFENAC 50 mg + 200 mcg comprime	not available	029316039	PFIZER ITALIA S.R.L.	IT
ARTROTEC 50 mg + 200 mcg comprime	not available	029757022	PFIZER ITALIA S.R.L.	IT
MISOFENAC 50 mg + 200 mcg comprime	not available	029316015	PFIZER ITALIA S.R.L.	IT
ARTROTEC 50 mg + 200 mcg comprime	not available	029757010	PFIZER ITALIA S.R.L.	IT
Arthrotec Forte, tabletter med modificerad frisättning	UK/H/0136/001	13276	PFIZER AB	SE
Arthrotec 75, 75 mg + 0,2 mg, comprimidos de libertação modificada	UK/H/0136/001	2536084	LABORATÓRIOS PFIZER, LDA.	PT
ARTHROTEC, 50 mg + 0,2 mg, tabletki	not available	7964	PFIZER EUROPE MA EEIG	PL
Arthrotec 75, 75 mg + 0,2 mg, comprimidos de libertação modificada	UK/H/0136/001	2536183	LABORATÓRIOS PFIZER, LDA.	PT
ARTHROTEC Forte, 75 mg + 0,2 mg, tabletki	not available	4221	PFIZER EUROPE MA EEIG	PL

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Arthrotec 75, 75 mg + 0,2 mg, comprimidos de libertação modificada	UK/H/0136/001	4029385	LABORATÓRIOS PFIZER, LDA.	PT
Arthrotec 75, 75 mg + 0,2 mg, comprimidos de libertação modificada	UK/H/0136/001	4028981	LABORATÓRIOS PFIZER, LDA.	PT
Arthrotec 75, 75 mg + 0,2 mg, comprimidos de libertação modificada	UK/H/0136/001	4029088	LABORATÓRIOS PFIZER, LDA.	PT
Arthrotec 75, 75 mg + 0,2 mg, comprimidos de libertação modificada	UK/H/0136/001	4029286	LABORATÓRIOS PFIZER, LDA.	PT
Arthrotec 75, 75 mg + 0,2 mg, comprimidos de libertação modificada	UK/H/0136/001	4029187	LABORATÓRIOS PFIZER, LDA.	PT
Misofenac 75 compresse a rilascio modificato	UK/H/0136/001	029316041	PFIZER ITALIA S.R.L.	IT
Arthrotec Forte, tabletter	not available	18455	PFIZER APS	DK
Misofenac 75 compresse a rilascio modificato	UK/H/0136/001	029316054	PFIZER ITALIA S.R.L.	IT
Arthotec® forte Manteltabletten mit 75 mg Diclofenac-Natrium und 0,2 mg Misoprostol	not available	40421.00.00	PFIZER PHARMA PFE GMBH	DE
MISOFENAC 50 mg + 200 mcg compresse	not available	029316027	PFIZER ITALIA S.R.L.	IT
Artrotec 75 compresse a rilascio modificato	UK/H/0136/001	029757046	PFIZER ITALIA S.R.L.	IT

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ARTHROTEC 75 mg/ 0,2 mg comprimato gastrorresistente	not available	5640/2005/02	PFIZER EUROPE MA EEIG	RO
Arthrotec 50 mg /200 microgramos comprimidos recubiertos	not available	61.079	PFIZER, S.L.	ES
Arthrotec 75 compresse a rilascio modificato	UK/H/0136/001	029757059	PFIZER ITALIA S.R.L.	IT
Arthrotec 75 comprimés à libération modifiée	UK/H/0136/001	2009050435	CONTINENTAL PHARMA, INC.	LU
Arthrotec® 75, Tabletten mit veränderter Wirkstofffreisetzung Diclofenac-Natrium, Misoprostol	UK/H/0136/001	2009050435	CONTINENTAL PHARMA, INC.	LU
Arthrotec 50, tabletten met gereguleerde afgifte	not available	RVG 16410	PFIZER B.V.	NL
ARTOTEC 50 mg/0,2 mg, comprimé gastro-résistant	not available	34009 336 490 3 6	PFIZER HOLDING FRANCE	FR
ARTOTEC 75 mg/0,2 mg, comprimé gastro-résistant	not available	34009 352 653 0 2	PFIZER HOLDING FRANCE	FR
ARTOTEC 50 mg/0,2 mg, comprimé gastro-résistant	not available	34009 336 495 5 5	PFIZER HOLDING FRANCE	FR
Arthrotec 75 modified-release tablets	UK/H/0136/001	PL 00057/0932	PFIZER LIMITED	UK
ARTOTEC 50 mg/0,2 mg, comprimé gastro-résistant	not available	34009 336 492 6 5	PFIZER HOLDING FRANCE	FR
ARTOTEC 75 mg/0,2 mg, comprimé gastro-résistant	not available	34009 352 655 3 1	PFIZER HOLDING FRANCE	FR

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ARTOTEC 50 mg/0,2 mg, comprimé gastro-résistant	not available	34009 336 494 9 4	PFIZER HOLDING FRANCE	FR
ARTOTEC 50 mg/0,2 mg, comprimé gastro-résistant	not available	34009 336 493 2 6	PFIZER HOLDING FRANCE	FR
Arthrotec 75, tabletten met gereguleerde afgifte	UK/H/0136/001	RVG 20871	PFIZER B.V.	NL
ARTOTEC 75 mg/0,2 mg, comprimé gastro-résistant	not available	34009 352 652 4 1	PFIZER HOLDING FRANCE	FR
ARTOTEC 75 mg/0,2 mg, comprimé gastro-résistant	not available	34009 352 654 7 0	PFIZER HOLDING FRANCE	FR
Arthrotec 50 modified-release tablets	not available	PL 00057/0931	PFIZER LIMITED	UK
Arthrotec Forte säädellysti vapauttava tabletti	UK/H/0136/001	12480	PFIZER OY	FI
Arthrotec 50 mg/0,2 mg, tabletter med modifierad frisättning	not available	11657	PFIZER AB	SE