



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 May 2019
EMA/282073/20199
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: misoprostol (gynaecological indication - labour induction)

Procedure no.: PSUSA/00010353/201805



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
Angusta 25 micrograme comprimate	DK/H/2584/001	10684/2018/01	AZANTA DANMARK A/S	RO
ANGUSTA 25 microgrammes, comprimé	DK/H/2584/001	34009 550 495 3 1	AZANTA DANMARK A/S	FR
Angusta 25 micrograms tablets	DK/H/2584/001	20180117	AZANTA DANMARK A/S	BG
Angusta 25 mikrog tabletit	DK/H/2584/001/DC	54486	AZANTA	FI
Angusta 25 míkroóg töflur	DK/H/2584/001	IS/1/16/104/01	AZANTA DANMARK A/S	IS
Angusta 25 mikrogramm tabletter	DK/H/2584/001	16-11107	AZANTA DANMARK A/S	NO
Angusta 25 mikrogramm tabletter	DK/H/2584/001	54486	AZANTA DANMARK A/S	SE
Angusta 25 mikrograma tablete	DK/H/2584/001	HR-H-356578013	AZANTA DANMARK A/S	HR
Angusta 25 mikrogrami tabletes	DK/H/2584/001	18-0010	AZANTA DANMARK A/S	LV
Angusta 25 mikrogramm tabletta	DK/H/2584/001	OGYI-T-23336/01	AZANTA DANMARK A/S	HU
Angusta 25 mikrogrammi tabletid	DK/H/2584/001	958718	AZANTA DANMARK A/S	EE
Angusta 25 mikrogramov tablete	DK/H/2485/001	H/18/02450/001	AZANTA DANMARK A/S	SI
Angusta 25 mikrogramov tablety	DK/H/2584/001	81/0039/18-S	AZANTA DANMARK A/S	SK
Angusta 25 mikrogramů tablety	DK/H/2584/001	54/370/17-C	AZANTA DANMARK A/S	CZ
Angusta, 25 mikrogramów, tabletki	DK/H/2584/001	24780	AZANTA DANMARK A/S	PL
Angusta, tabletter	DK/H/2584/001	57452	AZANTA DANMARK A/S	DK
Misodel 0,2 mg sistema de libertação vaginal	SE/H/1224/01	5616354	FERRING PORTUGUESA – PRODUTOS FARMACÊUTICOS, SOCIEDADE UNIPessoal, LDA.	PT
Misodel 0,2 mg sistema de libertação vaginal	SE/H/1224/01	5616362	FERRING PORTUGUESA – PRODUTOS FARMACÊUTICOS,	PT

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			SOCIEDADE UNIPessoal, LDA.	
Misodel 0,2 mg sistema de libertação vaginal	SE/H/1224/001	5616370	FERRING PORTUGUESA – PRODUTOS FARMACÊUTICOS, SOCIEDADE UNIPessoal, LDA.	PT
Misodel 200 microgram, hulpmiddel voor vaginaal gebruik	SE/H/1224/001	RVG 112566	FERRING B.V.	NL
Misodel 200 micrograme sistem cu cedare vaginală	SE/H/1224/001	6162/2014/01	FERRING GMBH	RO
Misodel 200 micrograme sistem cu cedare vaginală	SE/H/1224/001	6162/2014/02	FERRING GMBH	RO
Misodel 200 micrograme sistem cu cedare vaginală	SE/H/1224/001	6162/2014/03	FERRING GMBH	RO
Misodel 200 mikrog depotlääkevalmiste, emättimeen	SE/H/1224/001	31017	FERRING LÄÄKKEET OY	FI
Misodel 200 mÍróg skeiðarinnlegg	SE/H/1224/001	IS/1/13/092/01	FERRING LÆGEMIDLER A/S	IS
Misodel 200 mikrogram vaginalinlägg	SE/H/1224/001	31017	FERRING LÄÄKKEET OY	FI
Misodel 200 mikrogram vaginalinlägg	SE/H/1224/001	48411	FERRING LÄKEMEDEL AB	SE
Misodel 200 mikrogram vaginalinnlegg	SE/H/1224/001	12-9206	FERRING LEGEMIDLER AS	NO
Misodel 200 mikrogrami vaginālās ievadišanas sistēma	SE/H/1224/001	13-0264	FERRING GMBH	LV
Misodel 200 mikrogramm hüvelyben alkalmazott gyógyszerleadó rendszer	SE/H/1224/001	OGYI-T-22575/01	FERRING MAGYARORSZÁG GYÓGYSZERKERESKEDELMI KFT.	HU
Misodel 200 Mikrogramm vaginales Wirkstofffreisetzungssystem	SE/H/1224/001	135351	FERRING ARZNEIMITTEL GES.M.B.H.	AT

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MISODEL 200 Mikrogramm vaginales Wirkstofffreisetzungssystem	SE/H/1224/001	87587.00.00	FERRING ARZNEIMITTEL GMBH	DE
Misodel 200 mikrogramov vaginálny inžert	SE/H/1224/001	81/0476/13-S	FERRING LÉCIVA A.S.	SK
Misodel 200 mikrogramů vaginální inžert	SE/H/1224/001	54/123/14-C	FERRING PHARMACEUTICALS CZ S.R.O.	CZ
Misodel 200 mikrogramų vartojimo į makštį sistema	SE/H/1224/001	LT/1/13/3442/001	FERRING GMBH	LT
Misodel 200 mikrogramų vartojimo į makštį sistema	SE/H/1224/001	LT/1/13/3442/002	FERRING GMBH	LT
Misodel 200 mikrogramų vartojimo į makštį sistema	SE/H/1224/001	LT/1/13/3442/003	FERRING GMBH	LT
Misodel 200 μικρογραμμάρια σύστημα για ενδοκολπική χορήγηση	SE/H/1224/001	021987	FERRING PHARMACEUTICALS A/S	CY
Misodel 200 μικρογραμμάρια σύστημα για ενδοκολπική χορήγηση	SE/H/1224/001	53822/19-6-2014	FERRING HELLAS MEPE	GR
Misodel, 200 mikrogramów, system terapeutyczny dopochwowy	SE/H/1224/001	21677	FERRING GMBH	PL
Misodel, vaginalindlæg	SE/H/1224/001	51419	FERRING LÆGEMIDLER A/S	DK
Misofar 200 microgramos comprimidos vaginales	not available	69.683	LABORATORIOS BIAL, S.A.	ES
Misofar 25 microgramos comprimidos vaginales	not available	69.682	LABORATORIOS BIAL, S.A.	ES
Misofar 25 microgramos comprimidos vaginales	not available	69.682	LABORATORIOS BIAL, S.A.	ES
Mysodelle 200 microgram hulpmiddel voor vaginaal gebruik	SE/H/1224/001	BE445866	FERRING N.V.	BE
Mysodelle 200 microgrammes système de diffusion vaginal	SE/H/1224/001	BE445866	FERRING N.V.	BE

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Mysodelle 200 microgrammes système de diffusion vaginal	SE/H/1224/001	2014090262	FERRING N.V.	LU
Mysodelle 200 microgrammi dispositivo vaginale	SE/H/1224/001	042447019	FERRING S.P.A.	IT
Mysodelle 200 microgrammi dispositivo vaginale	SE/H/1224/001	042447021	FERRING S.P.A.	IT
Mysodelle 200 microgrammi dispositivo vaginale	SE/H/1224/001	042447033	FERRING S.P.A.	IT
Mysodelle 200 micrograms Vaginal Delivery System	SE/H/1224/001	PA 1009/025/001	FERRING IRELAND LTD.	IE
Mysodelle 200 micrograms vaginal delivery system	SE/H/1224/001	MA832/01001	FERRING PHARMACEUTICALS LTD.	MT
Mysodelle 200 micrograms vaginal delivery system.	SE/H/1224/001	PL 03194/0112	FERRING PHARMACEUTICALS LTD.	UK
Mysodelle 200 Mikrogramm vaginales Wirkstofffreisetzungssystem	SE/H/1224/001	BE445866	FERRING N.V.	BE
Mysodelle 200 Mikrogramm vaginales Wirkstofffreisetzungssystem	SE/H/1224/001	2014090262	FERRING N.V.	LU
Mysodelle 200 mikrogrammi vaginaalravivahend	SE/H/1224/001	830713	FERRING GMBH	EE
Mysodelle 200 mikrogramov vaginalni dostavni sistem	SE/H/1224/001	5363-I-418/14	FERRING GMBH	SI
Mysodelle 200 mikrogramov vaginalni dostavni sistem	SE/H/1224/001	5363-I-419/14	FERRING GMBH	SI
Mysodelle 200 mikrogramov vaginalni dostavni sistem	SE/H/1224/001	5363-I-420/14	FERRING GMBH	SI
Мизодел 200 микрограма вагинална лекарстводоставяща система	SE/H/1224/001	II-28388/10-02-2015	FERRING GMBH	BG