



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 January 2018
EMA/11926/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: misoprostol (gynaecological indication labour induction)

Procedure no.: PSUSA/00010353/201705



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, tabletter	DK/H/2584/001	57452	AZANTA DANMARK A/S	DK
Angusta 25 mikrogram tabletter	DK/H/2584/001	16-11107	AZANTA DANMARK A/S	NO
Angusta 25 míkroóg töflur	DK/H/2584/001	IS/1/16/104/01	AZANTA DANMARK A/S	IS
Angusta 25 mikrog tabletit	DK/H/2584/001/DC	34057	AZANTA	FI
Angusta 25 mikrogram tabletter	DK/H/2584/001	54486	AZANTA DANMARK A/S	SE
Misodel 200 mikrog depotlääkevalmiste, emättimeen	SE/H/1224/001	31017	FERRING LÄÄKKEET OY	FI
Misodel 200 microgram, hulpmiddel voor vaginaal gebruik	SE/H/1224/001	RVG 112566	FERRING B.V.	NL
Misodel 200 μικρογραμμάρια σύστημα για ενδοκολπική χορήγηση	SE/H/1224/001	53822/19-6-2014	FERRING HELLAS MEPE	GR
Misodel 200 μικρογραμμάρια σύστημα για ενδοκολπική χορήγηση	SE/H/1224/001	021987	FERRING PHARMACEUTICALS A/S	CY
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, SOCIEDADE UNIPessoal, LDA.	PT
Misodel 0,2 mg sistema de libertação vaginal	SE/H/1224/001	5616370	FERRING PORTUGUESA – PRODUTOS FARMACÊUTICOS, SOCIEDADE UNIPessoal, LDA.	PT

Misodel 200 Mikrogramm vaginales Wirkstofffreisetzungssystem	SE/H/1224/001	135351	FERRING ARZNEIMITTEL GES.M.B.H.	AT
Misodel 200 mikrogramů vaginální inzerť	SE/H/1224/001	54/123/14-C	FERRING PHARMACEUTICALS CZ S.R.O.	CZ
MISODEL 200 Mikrogramm vaginales Wirkstofffreisetzungssystem	SE/H/1224/001	87587.00.00	FERRING ARZNEIMITTEL GMBH	DE
Mysodelle 200 mikrogrammi vaginaalravivahend	SE/H/1224/001	830713	FERRING GMBH	EE
Misodel 200 microgramos sistema de liberación vaginal	SE/H/1224/001	78573	FERRING S.A.U.	ES
Misodel 200 microgrammes, dispositif de diffusion vaginal	SE/H/1224/001	586 168-1 OU 34009 586 168 1 5	FERRING S.A.S.	FR
Misodel 200 microgrammes, dispositif de diffusion vaginal	SE/H/1224/001	586 169-8 OU 34009 586 169 8 3	FERRING S.A.S.	FR
Misodel 200 microgrammes, dispositif de diffusion vaginal	SE/H/1224/001	586 170-6 OU 34009 586 170 6 5	FERRING S.A.S.	FR
Misodel 200 mikróg skeiðarinnlegg	SE/H/1224/001	IS/1/13/092/01	FERRING LÆGEMIDLER A/S	IS
Misodel 200 mikrogrami vaginālās ievadišanas sistēma	SE/H/1224/001	13-0264	FERRING GMBH	LV
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 mikrogramu vartojimo i makšti sistema	SE/H/1224/001	LT/1/13/3442/003	FERRING GMBH	LT

Misodel 200 mikrogram vaginalinnlegg	SE/H/1224/001	12-9206	FERRING LEGEMIDLER AS	NO
Misodel, 200 mikrogramów, system terapeutyczny dopochwowy	SE/H/1224/001	21677	FERRING GMBH	PL
Misodel 200 micrograme sistem cu cedare vaginală	SE/H/1224/001	6162/2014/01	FERRING GMBH	RO
Misodel 200 mikrogram vaginalinlägg	SE/H/1224/001	48411	FERRING LÄKEMEDEL AB	SE
Misodel 200 mikrogramov vaginálny inzert	SE/H/1224/001	81/0476/13-S	FERRING LÉCIVA A.S.	SK
Mysodelle 200 microgrammes système de diffusion vaginal	SE/H/1224/001	BE445866	FERRING N.V.	BE
Mysodelle 200 microgram hulpmiddel voor vaginaal gebruik	SE/H/1224/001	BE445866	FERRING N.V.	BE
Mysodelle 200 micrograms Vaginal Delivery System	SE/H/1224/001	PA 1009/025/001	FERRING IRELAND LTD.	IE
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 microgrammes système de diffusion vaginal	SE/H/1224/001	2014090262	FERRING N.V.	LU
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
Misodel 200 mikrogramm hüvelyben alkalmazott gyógyszerleadó rendszer	SE/H/1224/001	OGYI-T-22575/01	FERRING MAGYARORSZÁG GYÓGYSZERKERESKEDELM KFT.	HU
Мизодел 200 микрограма вагинална лекарстводоставяща система	SE/H/1224/001	20150034	FERRING GMBH	BG
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 mikrogram vaginalinlägg	SE/H/1224/001	31017	FERRING LÄÄKKEET OY	FI
Mysodelle 200 micrograms vaginal delivery system.	SE/H/1224/001	PL 03194/0112	FERRING PHARMACEUTICALS LTD.	UK
Misodel, vaginalindlæg	SE/H/1224/001	51419	FERRING LÆGEMIDLER A/S	DK
Misofar 25 microgramos comprimidos vaginales	not available	69.682	LABORATORIOS BIAL, S.A.	ES
Misofar 200 microgramos comprimidos vaginales	not available	69.683	LABORATORIOS BIAL, S.A.	ES