



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 January 2017
EMA/173834/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: Misoprostol (gynaecological indication - labour induction)

Procedure no.: PSUSA/00010353/201605



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
Misofar 25 microgramos comprimidos vaginales	not available	69682	LABORATORIOS BIAL, S.A.	ES
Misofar 200 microgramos comprimidos vaginales	not available	69683	LABORATORIOS BIAL, S.A.	ES
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	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

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Misodel 0,2 mg sistema de libertação vaginal.	SE/H/1224/01/DC	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

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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 míkroóg 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 mikrogramu vartojimo i makšti 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

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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	BE445866 / 2014090262	FERRING N.V.	LU

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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 GYÓGYSZERKERESKEDELMI 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
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