



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 January 2020
EMA/36948/2020
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: misoprostol (gynaecological indication - labour induction)

Procedure no.: PSUSA/00010353/201905

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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, comprime	DK/H/2584/001	34009 550 495 3 1	AZANTA DANMARK A/S	FR
Angusta 25 mikrog tabletit	DK/H/2584/001	54486	AZANTA	FI
Angusta 25 míkroóg töflur	DK/H/2584/001	IS/1/16/104/01	AZANTA DANMARK A/S	IS
Angusta 25 mikrogram tabletter	DK/H/2584/001	16-11107	AZANTA DANMARK A/S	NO
Angusta 25 mikrogram 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

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Angusta 25 mikrogrammi tabletid	DK/H/2584/001	958718	AZANTA DANMARK A/S	EE
Angusta 25 mikrogramov tablete	DK/H/2584/001	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/1224/001	5616354	FERRING PORTUGUESA – PRODUTOS FARMACÊUTICOS, SOCIEDADE UNIPessoal, LDA.	PT
Misodel 0,2 mg sistema de libertação vaginal.	SE/H/1224/001	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,	PT

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			LDA.	
Misodel 200 mikrogram vaginalinlägg	SE/H/1224/001	48411	FERRING LÄKEMEDEL AB	SE
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
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
Ангуста 25 микрограма таблетки	DK/H/2584/001	BG/MA/MP-41359	AZANTA DANMARK A/S	BG