



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 January 2022
EMA/PRAC/15035/2022
Pharmacovigilance Risk Assessment Committee (PRAC)

List of nationally authorised medicinal products

Active substance(s): misoprostol (gynaecological indication - labour induction)

Procedure No.: PSUSA/00010353/202105



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	69.682	LABORATORIOS BIAL, S.A.	ES
Angusta, tabletter	DK/H/2584/001	57452	AZANTA DANMARK A/S	DK
Angusta 25 mikrogramm tabletter	DK/H/2584/001	16-11107	NORGINE B.V.	NO
Angusta 25 míkroóg töflur	DK/H/2584/001	IS/1/16/104/01	NORGINE B.V.	IS
Angusta 25 mikrog tabletit	DK/H/2584/001	34057	NORGINE B.V.	FI
Angusta 25 mikrogramm tabletter	DK/H/2584/001	54486	AZANTA DANMARK A/S	SE
Angusta 25 mikrogrammi tabletes	DK/H/2584/001	18-0010	NORGINE B.V.	LV
ANGUSTA 25 microgrammes, comprime	DK/H/2584/001	34009 550 495 3 1	NORGINE B.V.	FR
Angusta 25 mikrograma tablete	DK/H/2584/001	HR-H-356578013	NORGINE B.V.	HR
Angusta 25 mikrogrammi tabletid	DK/H/2584/001	958718	NORGINE B.V.	EE
Angusta 25 mikrogramov tablety	DK/H/2584/001	81/0039/18-S	NORGINE B.V.	SK
Angusta 25 mikrogramm tabletta	DK/H/2584/001	OGYI-T-23336/01	NORGINE B.V.	HU
Angusta 25 mikrogramů tablety	DK/H/2584/001	54/370/17-C	NORGINE B.V.	CZ
Angusta 25 mikrogramov tablete	DK/H/2584/001	H/18/02450/001	NORGINE B.V.	SI
Angusta, 25 mikrogramów, tabletki	DK/H/2584/001	24780	NORGINE B.V.	PL
Angusta 25 micrograme comprimate	DK/H/2584/001	10684/2018/01	NORGINE B.V.	RO
Ангуста 25 микрограма таблетки	DK/H/2584/001	20180117	NORGINE B.V.	BG
Angusta 25 microgram tablets	DK/H/2584/001	MA930/00401	NORGINE B.V.	MT
Angusta 25 microgram tabletten	DK/H/2584/001	RVG 126719	NORGINE B.V.	NL
Angusta® 25 Mikrogramm Tabletten	DK/H/2584/001	140316	NORGINE BV	AT

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Angusta 25 MICROGRAMOS COMPRIMIDOS	DK/H/2584/001	85394	AZANTA DANMARK A/S	ES
Angusta 25 Mikrogramm Tabletten	DK/H/2584/001	7000441.00.00	NORGINE BV	DE
ANGUSTA 25 microgram tabletten	DK/H/2584/001	BE573342	NORGINE B.V.	BE
Angusta 25 microgram tablets	DK/H/2584/001	PA1336/010/001	NORGINE B.V.	IE
Angusta 25 microgramas comprimidos	DK/H/2584/001	5801501	NORGINE PORTUGAL FARMACEUTICA UNIPessoal, LDA	PT
ANGUSTA 25 microgrammi compresse	DK/H/2584/001	048968010	NORGINE ITALIA S.R.L.	IT
ANGUSTA 25 microgrammes comprimés	DK/H/2584/001	2020120332	NORGINE B.V.	LU
Angusta 25 μικρογραμμάρων δισκία	DK/H/2584/001	023247	AZANTA DANMARK A/S	CY
Angusta 25 μικρογραμμάρων δισκία	DK/H/2584/001	22061/12-03-2021	AZANTA DANMARK A/S	GR