



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 May 2020
EMA/273043/2020
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: dinoprostone

Procedure no.: PSUSA/00001104/201909



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
Minprostin, 1 mg vaginalgel	not available	11204	PFIZER AB	SE
Minprostin, 2 mg vaginalgel	not available	11205	PFIZER AB	SE
Minprostin, vagitorier	not available	12115	PFIZER APS	DK
MINPROSTIN® E2 Vaginalgel 1 mg	not available	19724.00.00	PFIZER PHARMA PFE GMBH	DE
MINPROSTIN® E2 Vaginalgel 2 mg	not available	19724.01.00	PFIZER PHARMA PFE GMBH	DE
MINPROSTIN® E2 VAGINALTABLETTEN 3 mg	not available	4496.00.00	PFIZER PHARMA PFE GMBH	DE
Prepidil 0,5 mg gél	not available	OGYI-T-1454/01	PFIZER KFT.	HU
PREPIDIL 0,5 mg gel endocervical	not available	BE139571	PFIZER S.A. (BELGIUM)	BE
PREPIDIL 0,5 mg gel endocervical	not available	2007069302	PFIZER S.A. (BELGIUM)	LU

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
PREPIDIL 0,5 mg, endocervikální gel	not available	54/135/87-C	PFIZER, SPOL. S R.O.	CZ
PREPIDIL 0,5 mg/3 g GEL ENDOCERVICALE	not available	028439014	PFIZER ITALIA S.R.L.	IT
Prepidil 0,5 mg/3 g gel za cerviks	not available	UP/I-530-09/13-02/246	PFIZER CROATIA D.O.O.	HR
PREPIDIL 0,5 mg/3 g vaginálny gél	not available	54/0284/00-S	PFIZER EUROPE MA EEIG	SK
Prepidil 0,5 mg/3 g, gel voor endocervicaal gebruik	not available	RVG 12119	PFIZER B.V.	NL
PREPIDIL 1 mg/3 g GEL VAGINALE	not available	028439026	PFIZER ITALIA S.R.L.	IT
PREPIDIL 2 mg/3 g GEL VAGINALE	not available	028439038	PFIZER ITALIA S.R.L.	IT
PREPIDIL INTRACERVICAL, gel stérile intracervical	not available	34009 555 912 0 7	PFIZER HOLDING FRANCE	FR
PREPIDIL INTRACERVICAL, gel stérile intracervical	not available	34009 555 911 4 6	PFIZER HOLDING FRANCE	FR

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
Prepidil, 500 µg/3 g, żel do szyjki macicy	not available	R/1550	PFIZER EUROPE MA EEIG	PL
Prepidil® - Gel zur intrazervikalen Anwendung	not available	1-18931	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
PREPIDIL® Gel Gel mit 0,5 mg Dinoproston	not available	13120.00.00	PFIZER PHARMA PFE GMBH	DE
PROPESS 10 mg - Dispositivo vaginale	SE/H/0129/001	033372018	FERRING S.P.A.	IT
PROPESS 10 mg hulpmiddel voor vaginaal gebruik	SE/H/0129/001	BE193191	FERRING N.V.	BE
PROPESS 10 mg sistema de liberación vaginal	SE/H/0129/001	62.088	FERRING S.A.U.	ES
Propess 10 mg Sistema de libertação vaginal	SE/H/0129/001	2645885	FERRING PORTUGUESA - PRODUTOS FARMACÊUTICOS, SOCIEDADE UNIPessoal, LDA.	PT
PROPESS 10 mg système de diffusion vaginal	SE/H/0129/001	BE193191	FERRING N.V.	BE
PROPESS 10 mg système de diffusion vaginal	SE/H/0129/001	2008099924	FERRING N.V.	LU

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
PROPESS 10 mg vaginales Freisetzungssystem	SE/H/0129/001	1-22193	FERRING ARZNEIMITTEL GES.M.B.H.	AT
PROPESS 10 mg vaginales Freisetzungssystem	SE/H/0129/001	50120.00.00	FERRING GMBH	DE
PROPESS 10 mg vaginales Wirkstofffreisetzungssystem	SE/H/0129/001	BE193191	FERRING N.V.	BE
PROPESS 10 mg vaginales Wirkstofffreisetzungssystem	SE/H/0129/001	2008099924	FERRING N.V.	LU
Propess 10 mg vaginalinlägg	SE/H/0129/001	12973	FERRING LÄKEMEDEL AB	SE
PROPESS 10 mg, système de diffusion vaginal	not available	CIP34009 5619744 6	FERRING S.A.S.	FR
PROPESS 10mg vaginal delivery system	SE/H/0129/001	PL 03194/0084	FERRING PHARMACEUTICALS LTD.	UK
Propess, vaginaal toedieningssysteem 10 mg	SE/H/0129/001	RVG 21617	FERRING B.V.	NL
Propess, vaginalindlæg	SE/H/0129/001	18853	FERRING LÆGEMIDLER A/S	DK

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
Prostaglandina E2 Pfizer 10 mg/ml, solución para perfusión	not available	56.620	PFIZER, S.L.	ES
PROSTIN E2 0,5 mg comprimés	not available	BE111282	PFIZER S.A. (BELGIUM)	BE
PROSTIN E2 0,5 mg comprimés	not available	1987060886	PFIZER S.A. (BELGIUM)	LU
PROSTIN E2 0,75 mg Konzentrat zur Herstellung einer Infusionslösung	not available	BE130672	PFIZER S.A. (BELGIUM)	BE
PROSTIN E2 0,75 mg Konzentrat zur Herstellung einer Infusionslösung	not available	2006119116	PFIZER S.A. (BELGIUM)	LU
PROSTIN E2 1 mg gel vaginal	not available	BE149782	PFIZER S.A. (BELGIUM)	BE
PROSTIN E2 1 mg gel vaginal	not available	2006119114	PFIZER S.A. (BELGIUM)	LU
Prostin E2 1 mg Vaginal Gel.	not available	PA 822/178/1	PFIZER HEALTHCARE IRELAND	IE
PROSTIN E2 1 mg/3 g Gel Vaginal	not available	8771907	LABORATÓRIOS PFIZER, LDA.	PT

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
Prostin E2 1 mg/ml Concentrate for Solution for Infusion	not available	PA 822/133/3	PFIZER HEALTHCARE IRELAND	IE
PROSTIN E2 2 mg gel vaginal	not available	BE149773	PFIZER S.A. (BELGIUM)	BE
Prostin E2 2 mg gel za rodnicu	not available	UP/I-530-09/13-02/244	PFIZER CROATIA D.O.O.	HR
Prostin E2 2 mg Vaginal Gel	not available	PA 822/178/2	PFIZER HEALTHCARE IRELAND	IE
PROSTIN E2 2 mg Vaginalgel	not available	2006119115	PFIZER S.A. (BELGIUM)	LU
PROSTIN E2 2 mg/3 g Gel Vaginal	not available	8771915	LABORATÓRIOS PFIZER, LDA.	PT
PROSTIN E2 3 mg comprimés vaginaux	not available	BE135457	PFIZER S.A. (BELGIUM)	BE
PROSTIN E2 3 mg comprimés vaginaux	not available	1994103031	PFIZER S.A. (BELGIUM)	LU
PROSTIN E2 3 mg vaginální tablety	not available	81/177/86-C	PFIZER, SPOL. S R.O.	CZ

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
Prostin E2 3mg Vaginal Tablets	not available	PA 822/133/4	PFIZER HEALTHCARE IRELAND	IE
PROSTIN E2 5 mg Konzentrat zur Herstellung einer Infusionslösung	not available	BE130681	PFIZER S.A. (BELGIUM)	BE
PROSTIN E2 5 mg Konzentrat zur Herstellung einer Infusionslösung	not available	2006119117	PFIZER S.A. (BELGIUM)	LU
PROSTIN E2 GEL, 0,5 mg/3 g, gel endocervical	not available	8771923	LABORATÓRIOS PFIZER, LDA.	PT
Prostin E2 Sterile Solution 1 mg/ml	not available	PL 00057/1028	PFIZER LIMITED	UK
Prostin E2 Sterile Solution 10 mg/ml	not available	PL 00057/1030	PFIZER LIMITED	UK
Prostin E2 Sterile Solution 10 mg/ml	not available	PL 00057/1027	PFIZER LIMITED	UK
PROSTIN E2 tbl vag 3 mg vaginálne tablety	not available	81/0177/86-CS	PFIZER EUROPE MA EEIG	SK
Prostin E2 vaginal 3 mg hüvelytabletta	not available	OGYI-T-4427/01	PFIZER KFT.	HU

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
Prostin E2 Vaginal Gel 1 mg	not available	MA505/02202	PFIZER HELLAS, A.E.	MT
Prostin E2 Vaginal Gel 1 mg	not available	PL 00057/1029	PFIZER LIMITED	UK
Prostin E2 Vaginal Gel 2 mg	not available	MA505/02203	PFIZER HELLAS, A.E.	MT
Prostin E2 Vaginal Gel 2 mg	not available	PL 00057/1025	PFIZER LIMITED	UK
Prostin E2 Vaginal Tablets 3mg.	not available	PL 00057/1516	PFIZER LIMITED	UK
Prostin E2, gel voor vaginaal gebruik 1 mg	not available	RVG 13823	PFIZER B.V.	NL
Prostin E2, gel voor vaginaal gebruik 2 mg	not available	RVG 13824	PFIZER B.V.	NL
Prostin E2® 3 mg - Vaginaltabletten	not available	1-18362	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
PROSTINE E2 1 mg/3 g, gel vaginal	not available	34009 557 748 3 9	PFIZER HOLDING FRANCE	FR

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
PROSTINE E2 2 mg/3 g, gel vaginal	not available	34009 557 750 8 9	PFIZER HOLDING FRANCE	FR
PROSTIN E2 3mg κολπικά δισκία	not available	23268/21-06-1995	PFIZER HELLAS, A.E.	GR