



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 June 2017
EMA/376407/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: dinoprostone

Procedure no.: PSUSA/00001104/201609



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® - Gel zur intrazervikalen Anwendung	not available	1-18931	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
Prostin E2® 3 mg – Vaginaltabletten	not available	1-18362	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
Prostin E2® 5 mg/0,5 ml - Konzentrat zur Infusionsbereitung	not available	17.094	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
Prostin E2® 0,75 mg/0,75 ml - Konzentrat zur Infusionsbereitung	not available	17.093	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
PROPESS 10 mg vaginales Freisetzungssystem	SE/H/0129/001	1-22193	FERRING ARZNEIMITTEL GES.M.B.H.	AT
PROSTIN E2 0,5 mg Tabletten	not available	BE111282	PFIZER S.A. (BELGIUM)	BE
PROSTIN E2 3 mg Vaginaltabletten	not available	BE135457	PFIZER S.A. (BELGIUM)	BE
PROSTIN E2 2 mg Vaginalgel	not available	BE149773	PFIZER S.A. (BELGIUM)	BE
PROSTIN E2 1 mg Vaginalgel	not available	BE149782	PFIZER S.A. (BELGIUM)	BE
PROSTIN E2 0,75 mg Konzentrat zur Herstellung einer Infusionslösung	not available	BE130672	PFIZER S.A. (BELGIUM)	BE
PREPIDIL 0,5 mg Gel zur endozervikalen Anwendung	not available	BE139571	PFIZER S.A. (BELGIUM)	BE
PROSTIN E2 5 mg Konzentrat zur Herstellung einer Infusionslösung	not available	BE130681	PFIZER S.A. (BELGIUM)	BE
PROSTIN E2 0,5 mg comprimés	not available	BE111282	PFIZER S.A. (BELGIUM)	BE

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PROSTIN E2 3 mg comprimés vaginaux	not available	BE135457	PFIZER S.A. (BELGIUM)	BE
PROSTIN E2 5 mg solution à diluer pour perfusion	not available	BE130681	PFIZER S.A. (BELGIUM)	BE
PROSTIN E2 0,75 mg solution à diluer pour perfusion	not available	BE130672	PFIZER S.A. (BELGIUM)	BE
PROSTIN E2 2 mg gel vaginal	not available	BE149773	PFIZER S.A. (BELGIUM)	BE
PROSTIN E2 1 mg gel vaginal	not available	BE149782	PFIZER S.A. (BELGIUM)	BE
PREPIDIL 0,5 mg gel endocervical	not available	BE139571	PFIZER S.A. (BELGIUM)	BE
PREPIDIL 0,5 mg gel voor endocervicaal gebruik	not available	BE139571	PFIZER S.A. (BELGIUM)	BE
PROSTIN E2 0,5 mg tabletten	not available	BE111282	PFIZER S.A. (BELGIUM)	BE
PROSTIN E2 2 mg gel voor vaginaal gebruik	not available	BE149773	PFIZER S.A. (BELGIUM)	BE
PROSTIN E2 5 mg concentraat voor oplossing voor infusie	not available	BE130681	PFIZER S.A. (BELGIUM)	BE
PROSTIN E2 3 mg tabletten voor vaginaal gebruik	not available	BE135457	PFIZER S.A. (BELGIUM)	BE
PROSTIN E2 1 mg gel voor vaginaal gebruik	not available	BE149782	PFIZER S.A. (BELGIUM)	BE
PROSTIN E2 0,75 mg concentraat voor oplossing voor infusie	not available	BE130672	PFIZER S.A. (BELGIUM)	BE
PROPESS 10 mg système de diffusion vaginal	SE/H/0129/001	BE193191	FERRING N.V.	BE
PROPESS 10 mg hulpmiddel voor vaginaal gebruik	SE/H/0129/001	BE193191	FERRING N.V.	BE

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PROSTIN E2	not available	81/177/86-C	PFIZER, SPOL. S R.O.	CZ
PREPIDIL 0,5 mg, endocervikální gel	not available	54/135/87-C	PFIZER, SPOL. S R.O.	CZ
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
MINPROSTIN® E2 Vaginalgel 1 mg	not available	19724.00.00	PFIZER PHARMA PFE GMBH	DE
PREPIDIL® Gel Gel mit 0,5 mg Dinoproston	not available	13120.00.00	PFIZER PHARMA PFE GMBH	DE
PROPESS 10 mg vaginales Freisetzungssystem	SE/H/0129/001	50120.00.00	FERRING GMBH	DE
Minprostin	not available	12115	PFIZER APS	DK
Propess, vaginalindlæg	SE/H/0129/001	18853	FERRING LÆGEMIDLER A/S	DK
Prostaglandina E2 Pfizer 10 mg/ml, solución para perfusión	not available	56.620	PFIZER, S.L.	ES
Prostaglandina E2 Pfizer 0,5 mg, comprimidos	not available	56.619	PFIZER, S.L.	ES
Prepidil 0,5 mg, gel endocervical	not available	57.694	PFIZER, S.L.	ES
PROPESS 10 mg sistema de liberación vaginal	SE/H/0129/001	62.088	FERRING S.A.U.	ES
PROPESS 10 mg, système de diffusion vaginal	not available	CIP34009 5619744 6	FERRING S.A.S.	FR
PREPIDIL INTRACERVICAL, gel stérile intracervical	not available	34009 555 912 0 7	PFIZER HOLDING FRANCE (S.C.A.)	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 1 mg/ml, solution à diluer pour perfusion	not available	3400955484356	PFIZER HOLDING FRANCE (S.C.A.)	FR
PREPIDIL INTRACERVICAL, gel stérile intracervical	not available	34009 555 911 4 6	PFIZER HOLDING FRANCE (S.C.A.)	FR
PROSTINE E2 2 mg/3 g, gel vaginal	not available	34009 557 750 8 9	PFIZER HOLDING FRANCE (S.C.A.)	FR
PROSTINE E2 1 mg/3 g, gel vaginal	not available	34009 557 748 3 9	PFIZER HOLDING FRANCE (S.C.A.)	FR
PROSTIN E2(Dinoprostone)	not available	6951/11418/12-1-1984	PFIZER HELLAS, A.E.	GR
Prepidil 0,5 mg/3 g gel za cerviks	not available	UP/I-530-09/13-02/246	PFIZER CROATIA D.O.O.	HR
Prostin E2 2 mg gel za rodnicu	not available	UP/I-530-09/13-02/244	PFIZER CROATIA D.O.O.	HR
Prepidil 0,5 mg gél	not available	OGYI-T-1454/01	PFIZER KFT.	HU
Prostin E2 vaginal 3 mg hüvelytabletta	not available	OGYI-T-4427/01	PFIZER KFT.	HU
Prostin E2 1 mg/ml Concentrate for Solution for Infusion	not available	PA 822/133/3	PFIZER HEALTHCARE IRELAND	IE
Prostin E2 Vaginal Gel 1 mg	not available	PA 822/178/1	PFIZER HEALTHCARE IRELAND	IE
Prostin E2 3mg Vaginal Tablets	not available	PA 822/133/4	PFIZER HEALTHCARE IRELAND	IE
Prostin E2 Vaginal Gel 2 mg	not available	PA 822/178/2	PFIZER HEALTHCARE IRELAND	IE
PREPIDIL 0,5 mg/3 g GEL ENDOCERVICALE	not available	028439014	PFIZER ITALIA S.R.L.	IT
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

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PROSTIN E2 0,75 mg/0,75 ml SOLUZIONE PER INFUSIONE	not available	027114014	PFIZER ITALIA S.R.L.	IT
PROPESS 10 mg – Dispositivo vaginale	SE/H/0129/001	033372018	FERRING S.P.A.	IT
PROSTIN E2 2 mg Vaginalgel	not available	2006119115	PFIZER S.A. (BELGIUM)	LU
PROSTIN E2 1 mg Vaginalgel	not available	2006119114	PFIZER S.A. (BELGIUM)	LU
PROSTIN E2 3 mg Vaginaltabletten	not available	1994103031	PFIZER S.A. (BELGIUM)	LU
PROSTIN E2 0,75 mg Konzentrat zur Herstellung einer Infusionslösung	not available	2006119116	PFIZER S.A. (BELGIUM)	LU
PREPIDIL 0,5 mg Gel zur endozervikalen Anwendung	not available	2007069302	PFIZER S.A. (BELGIUM)	LU
PROSTIN E2 5 mg Konzentrat zur Herstellung einer Infusionslösung	not available	2006119117	PFIZER S.A. (BELGIUM)	LU
PROSTIN E2 0,5 mg Tabletten	not available	1987060886	PFIZER S.A. (BELGIUM)	LU
PROSTIN E2 3 mg comprimés vaginaux	not available	1994103031	PFIZER S.A. (BELGIUM)	LU
PROSTIN E2 5 mg solution à diluer pour perfusion	not available	2006119117	PFIZER S.A. (BELGIUM)	LU
PROSTIN E2 1 mg gel vaginal	not available	2006119114	PFIZER S.A. (BELGIUM)	LU
PROSTIN E2 0,75 mg solution à diluer pour perfusion	not available	2006119116	PFIZER S.A. (BELGIUM)	LU
PROSTIN E2 0,5 mg comprimés	not available	1987060886	PFIZER S.A. (BELGIUM)	LU

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PROSTIN E2 2 mg gel vaginal	not available	2006119115	PFIZER S.A. (BELGIUM)	LU
PREPIDIL 0,5 mg gel endocervical	not available	2007069302	PFIZER S.A. (BELGIUM)	LU
PROPESS 10 mg système de diffusion vaginal	SE/H/0129/001	2008099924	FERRING N.V.	LU
Prostin E2 Vaginal Gel 1 mg	not available	MA505/02202	PFIZER HELLAS, A.E.	MT
Prostin E2 Vaginal Gel 2 mg	not available	MA505/02203	PFIZER HELLAS, A.E.	MT
Prostin E2, gel voor vaginaal gebruik 2 mg	not available	RVG 13824	PFIZER B.V.	NL
Prepidil 0,5 mg/3 g, gel voor endocervicaal gebruik	not available	RVG 12119	PFIZER B.V.	NL
Prostin E2, gel voor vaginaal gebruik 1 mg	not available	RVG 13823	PFIZER B.V.	NL
Propess, vaginaal toedieningssysteem 10mg	SE/H/0129/001	RVG 21617	FERRING B.V.	NL
Minprostin 0,5 mg / 2,5 ml endocervikalgel	not available	7281	PFIZER AS	NO
Prepidil, 500 µg/3 g, żel do szyjki macicy	not available	R/1550	PFIZER EUROPE MA EEIG	PL
PROSTIN E2 1 mg/3 g Gel Vaginal	not available	8771907	LABORATÓRIOS PFIZER, LDA.	PT
PROSTIN E2 2 mg/3 g Gel Vaginal	not available	8771915	LABORATÓRIOS PFIZER, LDA.	PT
PROSTIN E2 GEL, 0,5 mg/3 g, gel endocervical	not available	8771923	LABORATÓRIOS PFIZER, LDA.	PT
Prostin E2 0,5 mg comprimidos	not available	8449504	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
PROPESS 10 mg, Sistema de libertação vaginal	SE/H/0129/001	2645885	FERRING PORTUGUESA – PRODUTOS FARMACÊUTICOS, SOCIEDADE UNIPessoal, LDA.	PT
Minprostin, 2 mg vaginalgel	not available	11205	PFIZER AB	SE
Minprostin, 1 mg vaginalgel	not available	11204	PFIZER AB	SE
Propess 10 mg vaginalinlägg	SE/H/0129/001	12973	FERRING LÄKEMEDEL AB	SE
PROSTIN E2 tbl vag 3mg vaginálne tablety	not available	81/0177/86-C/S	PFIZER EUROPE MA EEIG	SK
PREPIDIL 0,5 mg/3 g vaginálny gél	not available	54/0284/00-S	PFIZER EUROPE MA EEIG	SK
Prostin E2 Sterile Solution 1 mg/ml	not available	PL 00057/1028	PFIZER LIMITED	UK
Prostin E2 Vaginal Gel 1 mg	not available	PL 00057/1029	PFIZER LIMITED	UK
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 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