1 December 2022
EMA/931498/2022
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: epoprostenol

Procedure no.: PSUSA/00001242/202203

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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
Caripul 0,5 mg, Polvere e Solvente per Soluzione per Infusione	NL/H/2600/003	042119038	JANSSEN-CILAG INTERNATIONAL NV	IT
CARIPUL 0,5 mg, Polvere per Soluzione per Infusione	NL/H/2600/001	042119014	JANSSEN-CILAG INTERNATIONAL NV	IT
CARIPUL 1,5 mg, Polvere e Solvente per Soluzione per Infusione	NL/H/2600/004	042119040	JANSSEN-CILAG INTERNATIONAL NV	IT
CARIPUL 1,5 mg, Polvere per Soluzione per Infusione	NL/H/2600/002	042119026	JANSSEN-CILAG INTERNATIONAL NV	IT
Epoprostenol 0.5 mg powder for solution for infusion	NL/H/3964/001	PL 31750/0137	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	XI
Epoprostenol 1.5 mg powder for solution for infusion	NL/H/3964/002	PL 31750/0138	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	XI
Epoprostenol NORMON 1,5 mg polvo para solución para perfusión.	not available	77784	LABORATORIOS NORMON, S.A.	ES
Epoprostenol SUN 0,5 mg poeder voor oplossing voor infusie	NL/H/3964/001	RVG 120936	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	NL
Epoprostenol SUN 1,5 mg polvo para solución para perfusión	NL/H/3964/002	83525	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	ES

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
Epoprostenol SUN 1,5 mg, poeder voor oplossing voor infusie	NL/H/3964/002	RVG 120937	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	NL
Epoprostenolo SUN 0,5 mg polvere per soluzione per infusione	NL/H/3964/001	045956012	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	IT
Epoprostenolo SUN 1,5 mg polvere per soluzione per infusione	NL/H/3964/002	045956024	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	IT
Flolan 0,5 mg - Pulver und Lösungsmittel zur Herstellung einer Infusionslösung	NL/H/2852/003	1-20059	GLAXOSMITHKLINE PHARMA GMBH.	AT
Flolan 0,5 mg – Pulver und Lösungsmittel zur Herstellung einer Infusionslösung	NL/H/2852/003	BE185595	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Flolan 0,5 mg – Pulver und Lösungsmittel zur Herstellung einer Infusionslösung	NL/H/2852/003	BE432196	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Flolan 0,5 mg – Pulver und Lösungsmittel zur Herstellung einer Infusionslösung	NL/H/2852/003	2003 10 7742	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
Flolan 0,5 mg – Pulver zur Herstellung einer Infusionslösung	NL/H/2852/004	BE432205	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE

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
Flolan 0,5 mg – Pulver zur Herstellung einer Infusionslösung	NL/H/2852/004	2014 04 0069	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
Flolan 0,5 mg poeder en oplosmiddel voor oplossing voor infusie	NL/H/2852/003	BE185595	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Flolan 0,5 mg poeder en oplosmiddel voor oplossing voor infusie	NL/H/2852/003	BE432196	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Flolan 0,5 mg poeder voor oplossing voor infusie	NL/H/2852/004	BE432205	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Flolan 0,5 mg poeder voor oplossing voor infusie	NL/H/2852/004	RVG 23523	GLAXOSMITHKLINE B.V.	NL
FLOLAN 0,5 mg polvere e solvente per soluzione per infusione	NL/H/2852/003	027750013	GLAXOSMITHKLINE (IRELAND) LIMITED	IT
FLOLAN 0,5 mg polvere per soluzione per infusione	NL/H/2852/004	027750025	GLAXOSMITHKLINE (IRELAND) LIMITED	IT
Flolan 0,5 mg polvo y disolvente para solución para perfusión.	NL/H/2852/003	57.757	GLAXOSMITHKLINE, S.A.	ES
Flolan 0,5 mg poudre et solvant pour solution pour perfusion	NL/H/2852/003	BE432196	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE

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
Flolan 0,5 mg poudre et solvant pour solution pour perfusion	NL/H/2852/003	BE185595	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Flolan 0,5 mg poudre et solvant pour solution pour perfusion	NL/H/2852/003	2003 10 7742	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
Flolan 0,5 mg poudre pour solution pour perfusion	NL/H/2852/004	BE432205	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Flolan 0,5 mg poudre pour solution pour perfusion	NL/H/2852/004	2014 04 0069	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
Flolan 0,5 mg prášek a rozpouštědlo pro infuzní roztok	NL/H/2852/003	83/383/01-C	GLAXOSMITHKLINE (IRELAND) LIMITED	CZ
Flolan 0,5 mg pulver og væske til infusjonsvæske, oppløsning	NL/H/2852/003	98-6812	GLAXOSMITHKLINE AS	NO
Flolan 0,5 mg, poeder en oplosmiddel voor oplossing voor infusie	NL/H/2852/003	RVG 14469	GLAXOSMITHKLINE B.V.	NL
Flolan 0.5 mg powder and solvent for solution for infusion	NL/H/2852/003	PA 1077/058/002	GLAXOSMITHKLINE (IRELAND) LIMITED	IE
Flolan 0.5 mg powder and solvent for solution for infusion	NL/H/2852/003	MA 192/02901	GLAXOSMITHKLINE (IRELAND) LIMITED	MT

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
Flolan 0.5 mg powder and solvent for solution for infusion	NL/H/2852/003	PL 10949/0310	GLAXO WELLCOME UK LTD	XI
Flolan 1,5 mg - Pulver und Lösungsmittel zur Herstellung einer Infusionslösung	NL/H/2852/001	1-23932	GLAXOSMITHKLINE PHARMA GMBH.	AT
Flolan 1,5 mg – Pulver und Lösungsmittel zur Herstellung einer Infusionslösung	NL/H/2852/001	BE214785	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Flolan 1,5 mg – Pulver und Lösungsmittel zur Herstellung einer Infusionslösung	NL/H/2852/001	BE432214	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Flolan 1,5 mg – Pulver und Lösungsmittel zur Herstellung einer Infusionslösung	NL/H/2852/001	2003 10 7743	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
Flolan 1,5 mg – Pulver zur Herstellung einer Infusionslösung	NL/H/2852/002	BE214794	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Flolan 1,5 mg – Pulver zur Herstellung einer Infusionslösung	NL/H/2852/002	2003 10 7741	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
Flolan 1,5 mg poeder en oplosmiddel voor oplossing voor infusie	NL/H/2852/001	BE214785	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE

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
Flolan 1,5 mg poeder en oplosmiddel voor oplossing voor infusie	NL/H/2852/001	BE432214	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Flolan 1,5 mg poeder voor oplossing voor infusie	NL/H/2852/002	BE214794	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
FLOLAN 1,5 mg polvere e solvente per soluzione per infusione	NL/H/2852/001	027750037	GLAXOSMITHKLINE (IRELAND) LIMITED	IT
Flolan 1,5 mg poudre et solvant pour solution pour perfusion	NL/H/2852/001	BE432214	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Flolan 1,5 mg poudre et solvant pour solution pour perfusion	NL/H/2852/001	BE214785	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Flolan 1,5 mg poudre et solvant pour solution pour perfusion	NL/H/2852/001	2003 10 7743	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
Flolan 1,5 mg poudre pour solution pour perfusion	NL/H/2852/002	BE214794	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Flolan 1,5 mg poudre pour solution pour perfusion	NL/H/2852/002	2003 10 7741	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
Flolan 1,5 mg pulver og væske til infusjonsvæske, oppløsning	NL/H/2852/001	06-3965	GLAXOSMITHKLINE AS	NO

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
Flolan 1,5 mg, poeder en oplosmiddel voor oplossing voor infusie	NL/H/2852/001	RVG 23525	GLAXOSMITHKLINE B.V.	NL
Flolan 1,5 mg, poeder voor oplossing voor infusie	NL/H/2852/002	RVG 23524	GLAXOSMITHKLINE B.V.	NL
Flolan 1,5 mg, prášek a rozpouštědlo pro infuzní roztok	NL/H/2852/001	83/384/01-C	GLAXOSMITHKLINE (IRELAND) LIMITED	CZ
Flolan 1.5 mg powder and solvent for solution for infusion	NL/H/2852/001	PA 1077/058/001	GLAXOSMITHKLINE (IRELAND) LIMITED	IE
Flolan 1.5 mg powder and solvent for solution for infusion	NL/H/2852/001	PL10949/0312	GLAXO WELLCOME UK LTD	XI
Flolan, 0,5 milligrammi infusioonilahuse pulber ja lahusti	NL/H/2852/003	307200	GLAXOSMITHKLINE (IRELAND) LIMITED	EE
Flolan, pulver og solvens til infusionsvæske, opløsning	NL/H/2852/003	13900	GLAXOSMITHKLINE PHARMA A/S	DK
Flolan, pulver og solvens til infusionsvæske, opløsning	NL/H/2852/001	30208	GLAXOSMITHKLINE PHARMA A/S	DK
VELETRI 0,5 mg polvo para solución para perfusión	NL/H/2600/001	81074	JANSSEN-CILAG INTERNATIONAL NV	ES

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
VELETRI 0,5 mg polvo y disolvente para solución para perfusión	NL/H/2600/003	81076	JANSSEN-CILAG INTERNATIONAL NV	ES
VELETRI 0,5 mg por oldatos infúzióhoz	NL/H/2723/001	OGYI-T-23058/01	JANSSEN-CILAG INTERNATIONAL NV	HU
VELETRI 0,5 mg poudre pour solution pour perfusion	NL/H/2723/001	2017040151	JANSSEN-CILAG INTERNATIONAL NV	LU
VELETRI 0,5 mg prášek pro infuzní roztok	NL/H/2600/001	83/361/13-C	JANSSEN-CILAG INTERNATIONAL NV	CZ
VELETRI 0,5 mg prášok na infúzny roztok	NL/H/2723/001	16/0397/16-S	JANSSEN-CILAG INTERNATIONAL NV	SK
VELETRI 0,5 mg Pulver zur Herstellung einer Infusionslösung	NL/H/2723/001	BE439747	JANSSEN-CILAG INTERNATIONAL NV	BE
VELETRI 0,5 mg Pulver zur Herstellung einer Infusionslösung	NL/H/2723/001	97089.00.00	JANSSEN-CILAG INTERNATIONAL NV	DE
VELETRI 0,5 mg Pulver zur Herstellung einer Infusionslösung	NL/H/2723/001	2017040151	JANSSEN-CILAG INTERNATIONAL NV	LU
VELETRI 0,5 mg, poeder en oplosmiddel voor oplossing voor infusie	NL/H/2600/003	RVG 111572	JANSSEN-CILAG INTERNATIONAL NV	NL

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
VELETRI 0,5 mg, poeder voor oplossing voor infusie	NL/H/2723/001	BE439747	JANSSEN-CILAG INTERNATIONAL NV	BE
VELETRI 0,5 mg, poeder voor oplossing voor infusie	NL/H/2723/001	RVG 112075	JANSSEN-CILAG INTERNATIONAL NV	NL
VELETRI 0,5 mg, poeder voor oplossing voor infusie	NL/H/2600/001	RVG 111570	JANSSEN-CILAG INTERNATIONAL NV	NL
VELETRI 0,5 mg, poudre et solvant pour solution pour perfusion	NL/H/2600/003	34009 585 763 3 1	JANSSEN-CILAG INTERNATIONAL NV	FR
VELETRI 0,5 mg, poudre pour solution pour perfusion	NL/H/2723/001	BE439747	JANSSEN-CILAG INTERNATIONAL NV	BE
VELETRI 0,5 mg, κόνις για διάλυμα προς ἐγχυση	NL/H/2723/001	96176/21-12-2016	JANSSEN-CILAG INTERNATIONAL NV	GR
VELETRI 0.5 mg poudre pour solution pour perfusion	NL/H/2600/001	34009 585 766 2 1	JANSSEN-CILAG INTERNATIONAL NV	FR
Veletri 0.5 mg, Powder for Solution for Infusion	NL/H/2600/001	PL 00242/0645	JANSSEN-CILAG LIMITED	XI
Veletri 0.5 Milligram Powder for Solution for Infusion	NL/H/2723/001	PA0885/001/001	JANSSEN-CILAG INTERNATIONAL NV	IE

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
VELETRI 1,5 mg polvo para solución para perfusión	NL/H/2600/002	81075	JANSSEN-CILAG INTERNATIONAL NV	ES
VELETRI 1,5 mg polvo y disolvente para solución para perfusión	NL/H/2600/004	81077	JANSSEN-CILAG INTERNATIONAL NV	ES
VELETRI 1,5 mg por oldatos infúzióhoz	NL/H/2723/002	OGYI-T-23058/02	JANSSEN-CILAG INTERNATIONAL NV	HU
VELETRI 1,5 mg prášek pro infuzní roztok	NL/H/2600/002	83/362/13-C	JANSSEN-CILAG INTERNATIONAL NV	CZ
VELETRI 1,5 mg prášok na infúzny roztok	NL/H/2723/002	16/0398/16-S	JANSSEN-CILAG INTERNATIONAL NV	SK
VELETRI 1,5 mg Pulver zur Herstellung einer Infusionslösung	NL/H/2723/002	BE439756	JANSSEN-CILAG INTERNATIONAL NV	BE
VELETRI 1,5 mg Pulver zur Herstellung einer Infusionslösung	NL/H/2723/002	97090.00.00	JANSSEN-CILAG INTERNATIONAL NV	DE
VELETRI 1,5 mg Pulver zur Herstellung einer Infusionslösung	NL/H/2723/002	2017040150	JANSSEN-CILAG INTERNATIONAL NV	LU
VELETRI 1,5 mg, poeder en oplosmiddel voor oplossing voor infusie	NL/H/2600/004	RVG 111573	JANSSEN-CILAG INTERNATIONAL NV	NL

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
VELETRI 1,5 mg, poeder voor oplossing voor infusie	NL/H/2723/002	BE439756	JANSSEN-CILAG INTERNATIONAL NV	BE
VELETRI 1,5 mg, poeder voor oplossing voor infusie	NL/H/2723/002	RVG 112076	JANSSEN-CILAG INTERNATIONAL NV	NL
VELETRI 1,5 mg, poeder voor oplossing voor infusie	NL/H/2600/002	RVG 111571	JANSSEN-CILAG INTERNATIONAL NV	NL
VELETRI 1,5 mg, poudre et solvant pour solution pour perfusion	NL/H/2600/004	34009 585 765 6 0	JANSSEN-CILAG INTERNATIONAL NV	FR
VELETRI 1,5 mg, poudre pour solution pour perfusion	NL/H/2723/002	BE439756	JANSSEN-CILAG INTERNATIONAL NV	BE
VELETRI 1,5 mg, poudre pour solution pour perfusion	NL/H/2600/002	34009 585 767 9 9	JANSSEN-CILAG INTERNATIONAL NV	FR
VELETRI 1,5 mg, poudre pour solution pour perfusion	NL/H/2723/002	2017040150	JANSSEN-CILAG INTERNATIONAL NV	LU
VELETRI 1,5 mg, κόνις για διάλυμα προς έγχυση	NL/H/2723/002	96177/21-12-2016	JANSSEN-CILAG INTERNATIONAL NV	GR
Veletri 1.5 mg, Powder for Solution for Infusion	NL/H/2600/002	PL 00242/0646	JANSSEN-CILAG LIMITED	XI

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
Veletri 1.5 Milligram Powder for Solution for Infusion	NL/H/2723/002	PA0885/001/002	JANSSEN-CILAG INTERNATIONAL NV	IE
Veletri de 0,5 mg, Pó para Solução para Perfusão	NL/H/2600/001	5586912	JANSSEN-CILAG INTERNATIONAL NV	PT
Veletri de 1,5 mg, Pó para Solução para Perfusão	NL/H/2600/002	5586920	JANSSEN-CILAG INTERNATIONAL NV	PT
VELETRI, 0,5 mg, proszek do sporządzania roztworu do infuzji	NL/H/2600/001	21530	JANSSEN-CILAG INTERNATIONAL NV	PL
VELETRI, 1,5 mg, proszek do sporządzania roztworu do infuzji	NL/H/2600/002	21531	JANSSEN-CILAG INTERNATIONAL NV	PL