



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 December 2017
EMA/46884/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance(s): epoprostenol

Procedure No.: PSUSA/00001242/201703



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/DC	042119038	ACTELION REGISTRATION LTD	IT
Caripul 0.5 mg Polvere per Soluzione per Infusione	NL/H/2600/001/DC	042119014	ACTELION REGISTRATION LTD	IT
Caripul 1.5 mg Polvere per Soluzione per Infusione	NL/H/2600/002/DC	042119026	ACTELION REGISTRATION LTD	IT
Caripul 1.5 mg Polvere e Solvente per Soluzione per Infusione	NL/H/2600/004/DC	042119040	ACTELION REGISTRATION LTD	IT
Epoprostenol NORMON 1,5 mg polvo para solución para perfusión	not available	77784	LABORATORIOS NORMON, S.A.	ES
Flolan	NL/H/2852/003	13900	GLAXOSMITHKLINE PHARMA A/S	DK
Flolan	NL/H/2852/001/MR	30208	GLAXOSMITHKLINE PHARMA A/S	DK
Flolan 0,5 mg - Pulver und Lösungsmittel zur Herstellung einer Infusionslösung	NL/H/2852/003/MR	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/MR	BE432196	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Flolan 0,5 mg – Pulver und Lösungsmittel zur Herstellung einer Infusionslösung	NL/H/2852/003	2003107742	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU

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Infusionslösung				
Flolan 0,5 mg – Pulver zur Herstellung einer Infusionslösung	NL/H/2852/004	BE432205	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
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/MR	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/MR	027750013	THE WELLCOME FOUNDATION LTD	IT
FLOLAN 0,5 mg Polvere per soluzione per infusione	NL/H/2852/004	027750025	THE WELLCOME FOUNDATION LTD	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/MR	BE432196	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
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	NL/H/2852/003	2003 10 7742	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU

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pour perfusion				
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 pulver og væske til infusionsvæske, opløsning	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, poudre et solvant pour solution pour perfusion	NL/H/2852/003	NL22893	LABORATOIRE GLAXOSMITHKLINE	FR
Flolan 0,5 mg, prášek a rozpouštědlo pro infuzní roztok	NL/H/2852/003	83/383/01-C	THE WELLCOME FOUNDATION LTD	CZ
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/MR	MA 167/01701	GLAXO WELLCOME UK LIMITED	MT
Flolan 1,5 mg - Pulver und Lösungsmittel zur Herstellung einer Infusionslösung	NL/H/2852/001/MR	1-23932	GLAXOSMITHKLINE PHARMA GMBH.	AT
Flolan 1,5 mg – Pulver und Lösungsmittel zur Herstellung einer Infusionslösung	NL/H/2852/001/MR	BE214785	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Flolan 1,5 mg – Pulver und Lösungsmittel zur	NL/H/2852/002	BE432214	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE

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Herstellung einer Infusionslösung				
Flolan 1,5 mg – Pulver und Lösungsmittel zur Herstellung einer Infusionslösung	NL/H/2852/001/MR	2003107743	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
Flolan 1,5 mg – Pulver zur Herstellung einer Infusionslösung	NL/H/2852/002/MR	BE214794	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Flolan 1,5 mg – Pulver zur Herstellung einer Infusionslösung	NL/H/2852/002/MR	2003107741	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
Flolan 1,5 mg poeder en oplosmiddel voor oplossing voor infusie	NL/H/2852/001/MR	BE214785	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Flolan 1,5 mg poeder en oplosmiddel voor oplossing voor infusie	NL/H/2852/001/MR	BE432214	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Flolan 1,5 mg poeder voor oplossing voor infusie	NL/H/2852/002/MR	BE214794	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Flolan 1,5 mg poudre et solvant pour solution pour perfusion	NL/H/2852/001/MR	BE432214	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Flolan 1,5 mg poudre et solvant pour solution pour perfusion	L/H/2852/001/MR	BE214785	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Flolan 1,5 mg poudre et solvant pour solution pour perfusion	NL/H/2852/001/MR	2003/10 7743	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
Flolan 1,5 mg poudre pour solution pour perfusion	NL/H/2852/002/MR	BE214794	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Flolan 1,5 mg poudre pour solution pour	NL/H/2852/002/MR	2003 10 7741	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU

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perfusion				
Flolan 1,5 mg pulver og væske til infusionsvæske, opløsning	NL/H/2852/001/MR	06-3965	GLAXOSMITHKLINE AS	NO
Flolan 1,5 mg, poeder en oplosmiddel voor oplossing voor infusie	NL/H/2852/001/MR	RVG 23525	GLAXOSMITHKLINE B.V.	NL
Flolan 1,5 mg, poeder voor oplossing voor infusie	NL/H/2852/002/MR	RVG 23524	GLAXOSMITHKLINE B.V.	NL
FLOLAN 1,5 mg, poudre et solvant pour solution pour perfusion	NL/H/2852/001/MR	NL22894	LABORATOIRE GLAXOSMITHKLINE	FR
Flolan 1,5 mg, prášek a rozpouštědlo pro infuzní roztok	NL/H/2852/001/MR	83/384/01-C	THE WELLCOME FOUNDATION LTD	CZ
FLOLAN 1,5 mg/50 ml Polvere e solvente per soluzione per infusione	NL/H/2852/001/MR	027750037	THE WELLCOME FOUNDATION LTD	IT
Flolan 1.5 mg powder and solvent for solution for infusion	NL/H/2852/001/MR	PA 1077/058/001	GLAXOSMITHKLINE (IRELAND) LIMITED	IE
Flolan, 0,5 milligrammi infusioonilahuse pulber ja lahusti	NL/H/2852/003	307200	GLAXO WELLCOME LTD	EE
Flolan® 0.5 mg powder and solvent for solution for infusion	NL/H/2852/004	PL 10949/0310	GLAXO WELLCOME UK LTD TRADING AS GLAXOSMITHKLINE UK	UK
Flolan® 1.5 mg powder and solvent for solution for infusion	NL/H/2852/002/MR	PL10949/0312	GLAXO WELLCOME UK LTD TRADING AS GLAXOSMITHKLINE UK	UK
VELETTRI 0,5 mg poudre pour solution pour perfusion	NL/H/2723/001/E/001	2017040151	ACTELION REGISTRATION LTD	LU
VELETTRI 0,5 mg proszek	NL/H/2600/003	22037	ACTELION REGISTRATION	PL

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i rozpuszczalnik do sporządzania roztworu do infuzji			LTD	
VELETRI 0,5 mg Pulver zur Herstellung einer Infusionslösung	NL/H/2723/001/E/001	2017040151	ACTELION LTD REGISTRATION	LU
VELETRI 0,5 mg, poudre pour solution pour perfusion	NL/H/2723/001	BE439747	ACTELION LTD REGISTRATION	BE
Veletri 0.5 mg Pó e Solvente para Solução para Perfusão	NL/H/2600/003/DC	NL/H/260/03/DC	ACTELION LTD REGISTRATION	PT
Veletri 0.5 mg Pó para Solução para Perfusão	NL/H/2600/001/DC	5586912	ACTELION LTD REGISTRATION	PT
Veletri 0.5 mg poeder en oplosmiddel voor oplossing voor infusie	NL/H/2600/003/DC	RVG 111572	ACTELION LTD REGISTRATION	NL
Veletri 0.5 mg poeder voor oplossing voor infusie	NL/H/2600/001/DC	RVG 111570	ACTELION LTD REGISTRATION	NL
Veletri 0.5 mg poeder voor oplossing voor infusie	NL/H/2723/001/DC	RVG 112075	ACTELION LTD REGISTRATION	NL
Veletri 0.5 mg polvo para solución para perfusión	NL/H/2723/001/DC	78019	ACTELION LTD REGISTRATION	ES
Veletri 0.5 mg por oldatos infúzióhoz	NL/H/2723/001/E/001	OGYI-T-23058/01	ACTELION LTD REGISTRATION	HU
Veletri 0.5 mg poudre et solvant pour solution pour perfusion	NL/H/2600/003/DC	585763-3, 3400958576331	ACTELION LTD REGISTRATION	FR
Veletri 0.5 mg poudre pour solution pour perfusion	NL/H/2600/001/DC	585766-2, 3400958576621	ACTELION LTD REGISTRATION	FR
Veletri 0.5 mg Powder for Solution for Infusion	NL/H/2723/001/E/001	PA 2094/001/001	ACTELION LTD REGISTRATION	IE
Veletri 0.5 mg POWDER	NL/H/2600/001/DC	PL 18900/0007	ACTELION REGISTRATION	UK

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FOR SOLUTION FOR INFUSION			LTD	
Veletri 0.5 mg prášek pro infuzní roztok	NL/H/2600/001/DC	83/361/13-C	ACTELION LTD REGISTRATION	CZ
Veletri 0.5 mg prášok na infúzny roztok	NL/H/2723/001/E/001	16/0397/16-S	ACTELION LTD REGISTRATION	SK
Veletri 0.5 mg proszek do sporządzania roztworu do infuzji	NL/H/2600/001/DC	21530	ACTELION LTD REGISTRATION	PL
Veletri 0.5 mg Pulver zur Herstellung einer Infusionslösung	NL/H/2723/001/E/001	97089.00.00	ACTELION LTD REGISTRATION	DE
Veletri 0.5 mg κόκκις για διάλυμα προς έγχυση	NL/H/2723/001/E/001	313390101	ACTELION LTD REGISTRATION	GR
VELETRI 1,5 mg proszek i rozpuszczalnik do sporządzania roztworu do infuzji	NL/H/2600/004	22038	ACTELION LTD REGISTRATION	PL
VELETRI 1,5 mg Pulver zur Herstellung einer Infusionslösung	NL/H/2723/002/E/001	2017040150	ACTELION LTD REGISTRATION	LU
VELETRI 1,5 mg, poudre pour solution pour perfusion	NL/H/2723/002	BE439756	ACTELION LTD REGISTRATION	BE
VELETRI 1,5 mg, poudre pour solution pour perfusion	NL/H/2723/002/E/001	2017040150	ACTELION LTD REGISTRATION	LU
Veletri 1.5 mg Pó e Solvente para Solução para Perfusão	NL/H/2600/004/DC	NL/H/2600/004/DC	ACTELION LTD REGISTRATION	PT
Veletri 1.5 mg Pó para Solução para Perfusão	NL/H/2600/002/DC	5586920	ACTELION LTD REGISTRATION	PT
Veletri 1.5 mg poeder en oplosmiddel voor oplossing voor infusie	NL/H/2600/004/DC	RVG 111573	ACTELION LTD REGISTRATION	NL
Veletri 1.5 mg poeder	NL/H/2600/002/DC	RVG 111571	ACTELION REGISTRATION	NL

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voor oplossing voor infusie			LTD	
Veletri 1.5 mg poeder voor oplossing voor infusie	NL/H/2723/002/DC	RVG 112076	ACTELION REGISTRATION LTD	NL
Veletri 1.5 mg polvo para solución para perfusión	NL/H/2723/002/DC	78020	ACTELION REGISTRATION LTD	ES
Veletri 1.5 mg por oldatos infúzióhoz	NL/H/2723/002/E/001	OGYI-T-23058/02	ACTELION REGISTRATION LTD	HU
Veletri 1.5 mg poudre et solvant pour solution pour perfusion	NL/H/2600/004/DC	585765-0, 3400958576560	ACTELION REGISTRATION LTD	FR
Veletri 1.5 mg poudre pour solution pour perfusion	NL/H/2600/002/DC	585767-9, 3400958576799	ACTELION REGISTRATION LTD	FR
Veletri 1.5 mg Powder for Solution for Infusion	NL/H/2723/002/E/001	PA 2094/001/002	ACTELION REGISTRATION LTD	IE
Veletri 1.5 mg POWDER FOR SOLUTION FOR INFUSION	NL/H/2600/002/DC	PL 18900/0008	ACTELION REGISTRATION LTD	UK
Veletri 1.5 mg prášek pro infuzní roztok	NL/H/2600/002/DC	83/362/13-C	ACTELION REGISTRATION LTD	CZ
Veletri 1.5 mg prášok na infúzny roztok	NL/H/2723/002/E/001	16/0398/16-S	ACTELION REGISTRATION LTD	SK
Veletri 1.5 mg proszek do sporządzenia roztworu do infuzji	NL/H/2600/002/DC	21531	ACTELION REGISTRATION LTD	PL
Veletri 1.5 mg Pulver zur Herstellung einer Infusionslösung	NL/H/2723/002/E/001	97090.00.00	ACTELION REGISTRATION LTD	DE
Veletri 1.5 mg κόνις για διάλυμα προς έγχυση	NL/H/2723/002/E/001	313390201	ACTELION REGISTRATION LTD	GR

