



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 January 2019
EMA/36490/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: treprostinil

Procedure no.: PSUSA/00003013/201805



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
REMODULIN 1 mg/ml, oplossing voor infusie	FR/H/0278/001	RVG32550	FERRER INTERNACIONAL, S.A.	NL
REMODULIN 2,5 mg/ml, oplossing voor infusie	FR/H/0278/002	RVG32551	FERRER INTERNACIONAL, S.A.	NL
Remodulin, infusionsvæske, opløsning 1 mg/ml	FR/H/0278/001	37978	FERRER INTERNACIONAL, S.A.	DK
Remodulin, infusionsvæske, opløsning 2,5 mg/ml	FR/H/0278/002	37979	FERRER INTERNACIONAL, S.A.	DK
Remodulin, infusionsvæske, opløsning 5 mg/ml	FR/H/0278/003	37980	FERRER INTERNACIONAL, S.A.	DK
Remodulin, infusionsvæske, opløsning 10 mg/ml	FR/H/0278/004	37981	FERRER INTERNACIONAL, S.A.	DK
REMODULIN 5 mg/ml, oplossing voor infusie	FR/H/0278/003	RVG32552	FERRER INTERNACIONAL, S.A.	NL
REMODULIN 10 mg/ml, oplossing voor infusie	FR/H/0278/004	RVG32553	FERRER INTERNACIONAL, S.A.	NL
Remodulin, 1 mg/ml solução para perfusão	FR/H/0278/001	5683081	FERRER INTERNACIONAL, S.A.	PT
Remodulin, 2,5 mg/ml solução para perfusão	FR/H/0278/002	5683180	FERRER INTERNACIONAL, S.A.	PT
Remodulin, 5 mg/ml solução para perfusão	FR/H/0278/003	5683289	FERRER INTERNACIONAL, S.A.	PT
Remodulin, 10 mg/ml solução para perfusão	FR/H/0278/004	5683388	FERRER INTERNACIONAL, S.A.	PT
REMODULIN 1 mg/ml, solution pour perfusion	FR/H/0278/001	6 863 597 4	FERRER INTERNACIONAL, S.A.	FR
REMODULIN 2,5 mg/ml, solution pour perfusion	FR/H/0278/002	6 093 728 7	FERRER INTERNACIONAL, S.A.	FR
REMODULIN 5 mg/ml, solution pour perfusion	FR/H/0278/003	6 692 392 8	FERRER INTERNACIONAL, S.A.	FR
REMODULIN 10 mg/ml, solution pour perfusion	FR/H/0278/004	6 521 301 0	FERRER INTERNACIONAL, S.A.	FR
Remodulin 1 mg/ml infusionsvæske, oppløsning	FR/H/0278/001	05/3455	FERRER INTERNACIONAL, S.A.	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
Remodulin 2,5 mg/ml infusjonsvæske, oppløsning	FR/H/0278/002	05/3456	FERRER INTERNACIONAL, S.A.	NO
Remodulin 5 mg/ml infusjonsvæske, oppløsning	FR/H/0278/003	05/3457	FERRER INTERNACIONAL, S.A.	NO
Remodulin 10 mg/ml infusjonsvæske, oppløsning	FR/H/0278/004	05/3458	FERRER INTERNACIONAL, S.A.	NO
Remodulin 1 mg/ml infúzny roztok	FR/H/0278/001	16/0315/05-S	FERRER INTERNACIONAL, S.A.	SK
Remodulin 2,5 mg/ml infúzny roztok	FR/H/0278/002	16/0316/05-S	FERRER INTERNACIONAL, S.A.	SK
Remodulin 5 mg/ml infúzny roztok	FR/H/0278/003	16/0317/05-S	FERRER INTERNACIONAL, S.A.	SK
Remodulin 10 mg/ml infúzny roztok	FR/H/0278/004	16/0318/05-S	FERRER INTERNACIONAL, S.A.	SK
REMOTULIN, 1 mg/ml infusioonilahus	FR/H/0278/001	504705	FERRER INTERNACIONAL, S.A.	EE
REMOTULIN, 2,5 mg/ml infusioonilahus	FR/H/0278/002	504505	FERRER INTERNACIONAL, S.A.	EE
REMOTULIN, 5 mg/ml infusioonilahus	FR/H/0278/003	504405	FERRER INTERNACIONAL, S.A.	EE
REMOTULIN, 10 mg/ml infusioonilahus	FR/H/0278/004	504605	FERRER INTERNACIONAL, S.A.	EE
REMOTULIN 1 mg/ml Infusionslösung	FR/H/0278/001	1-26454	FERRER INTERNACIONAL, S.A.	AT
REMOTULIN 2,5 mg/ml Infusionslösung	FR/H/0278/002	1-26521	FERRER INTERNACIONAL, S.A.	AT
REMOTULIN 5 mg/ml Infusionslösung	FR/H/0278/003	1-26522	FERRER INTERNACIONAL, S.A.	AT
REMOTULIN 10 mg/ml Infusionslösung	FR/H/0278/004	1-26523	FERRER INTERNACIONAL, S.A.	AT
REMOTULIN 1 mg/ml šķīdums infūzijām	FR/H/0278/001	07-0201	FERRER INTERNACIONAL, S.A.	LV
REMOTULIN 2,5 mg/ml šķīdums infūzijām	FR/H/0278/002	07-0202	FERRER INTERNACIONAL, S.A.	LV

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
REMODULIN 5 mg/ml šķīdums infūzijām	FR/H/0278/003	07-0203	FERRER INTERNACIONAL, S.A.	LV
REMODULIN 10 mg/ml šķīdums infūzijām	FR/H/0278/004	07-0204	FERRER INTERNACIONAL, S.A.	LV
Remodulin 1 mg/ml oldatos infúzió	FR/H/0278/001	OGYI-T-20185/01	FERRER INTERNACIONAL, S.A.	HU
Remodulin 2,5 mg/ml oldatos infúzió	FR/H/0278/002	OGYI-T-20185/02	FERRER INTERNACIONAL, S.A.	HU
Remodulin 5 mg/ml oldatos infúzió	FR/H/0278/003	OGYI-T-20185/03	FERRER INTERNACIONAL, S.A.	HU
Remodulin 10 mg/ml oldatos infúzió	FR/H/0278/004	OGYI-T-20185/04	FERRER INTERNACIONAL, S.A.	HU
Remodulin 1 mg/ml infuzinis tirpalas	FR/H/0278/001	LT/1/07/0903/001	FERRER INTERNACIONAL, S.A.	LT
Remodulin 2,5 mg/ml infuzinis tirpalas	FR/H/0278/002	LT/1/07/0903/002	FERRER INTERNACIONAL, S.A.	LT
Remodulin 5 mg/ml infuzinis tirpalas	FR/H/0278/003	LT/1/07/0903/003	FERRER INTERNACIONAL, S.A.	LT
Remodulin 10 mg/ml infuzinis tirpalas	FR/H/0278/004	LT/1/07/0903/004	FERRER INTERNACIONAL, S.A.	LT
REMODULIN 1 mg/ml Infuzní roztok	FR/H/0278/001	83/340/05-C	FERRER INTERNACIONAL, S.A.	CZ
REMODULIN 2,5 mg/ml Infuzní roztok	FR/H/0278/002	83/341/05-C	FERRER INTERNACIONAL, S.A.	CZ
REMODULIN 5 mg/ml Infuzní roztok	FR/H/0278/003	83/342/05-C	FERRER INTERNACIONAL, S.A.	CZ
REMODULIN 10 mg/ml Infuzní roztok	FR/H/0278/004	83/343/05-C	FERRER INTERNACIONAL, S.A.	CZ
Remodulin 1 mg/ml, solution pour perfusion	FR/H/0278/001	BE296362	FERRER INTERNACIONAL, S.A.	BE
Remodulin 2,5 mg/ml, solution pour perfusion	FR/H/0278/002	BE296371	FERRER INTERNACIONAL, S.A.	BE
Remodulin 5 mg/ml, solution pour perfusion	FR/H/0278/003	BE296387	FERRER INTERNACIONAL, S.A.	BE
Remodulin 10 mg/ml, solution pour perfusion	FR/H/0278/004	BE296396	FERRER INTERNACIONAL, S.A.	BE
Remodulin 1 mg/ml,	FR/H/0278/001	BE296362	FERRER INTERNACIONAL,	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
oplossing voor infusie.			S.A.	
Remodulin 2,5 mg/ml, oplossing voor infusie.	FR/H/0278/002	BE296371	FERRER INTERNACIONAL, S.A.	BE
Remodulin 5 mg/ml, oplossing voor infusie.	FR/H/0278/003	BE296387	FERRER INTERNACIONAL, S.A.	BE
Remodulin 10 mg/ml, oplossing voor infusie.	FR/H/0278/004	BE296396	FERRER INTERNACIONAL, S.A.	BE
REMODULIN 1 mg/ml infuusioneste, liuos.	FR/H/0278/001	21101	FERRER INTERNACIONAL, S.A.	FI
REMODULIN 2,5 mg/ml infuusioneste, liuos.	FR/H/0278/002	21103	FERRER INTERNACIONAL, S.A.	FI
REMODULIN 5 mg/ml infuusioneste, liuos.	FR/H/0278/003	21104	FERRER INTERNACIONAL, S.A.	FI
REMODULIN 10 mg/ml infuusioneste, liuos.	FR/H/0278/004	21102	FERRER INTERNACIONAL, S.A.	FI
REMODULIN, 5 mg/ml διάλυμα για έγχυση	FR/H/0278/003	20897/03-04-2012	FERRER-GALENICA S.A.	GR
REMODULIN, 1 mg/ml διάλυμα για έγχυση	FR/H/0278/001	20895/03-04-2012	FERRER-GALENICA S.A.	GR
REMODULIN, 2,5 mg/ml διάλυμα για έγχυση	FR/H/0278/002	20896/03-04-2012	FERRER-GALENICA S.A.	GR
REMODULIN, 10 mg/ml διάλυμα για έγχυση	FR/H/0278/004	20898/03-04-2012	FERRER-GALENICA S.A.	GR
REMODULIN 1 mg/ml infusionsvätska, lösning	FR/H/0278/001-004	22464	FERRER INTERNACIONAL, S.A.	SE
REMODULIN 2,5 mg/ml infusionsvätska, lösning	FR/H/0278/001-004	22465	FERRER INTERNACIONAL, S.A.	SE
REMODULIN 5 mg/ml infusionsvätska, lösning	FR/H/0278/001-004	22466	FERRER INTERNACIONAL, S.A.	SE
REMODULIN 10 mg/ml infusionsvätska, lösning	FR/H/0278/001-004	22467	FERRER INTERNACIONAL, S.A.	SE
Remodulin 1 mg/ml otopina za infuziju	FR/H/0278/001-004	UP/I-530-09/13-02/172	FERRER INTERNACIONAL, S.A.	HR
Remodulin 2,5 mg/ml otopina za infuziju	FR/H/0278/001-004	UP/I-530-09/13-02/173	FERRER INTERNACIONAL, S.A.	HR
Remodulin 5 mg/ml otopina za infuziju	FR/H/0278/001-004	UP/I-530-09/13-02/174	FERRER INTERNACIONAL, S.A.	HR

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
Remodulin 10 mg/ml otopina za infuziju	FR/H/0278/001-004	UP/I-530-09/13-02/175	FERRER INTERNACIONAL, S.A.	HR
Remodulin 1 mg/ml, solution pour perfusion	FR/H/0278/001	1648/05100103	FERRER INTERNACIONAL, S.A.	LU
Remodulin 2,5 mg/ml, solution pour perfusion	FR/H/0278/002	1648/05100104	FERRER INTERNACIONAL, S.A.	LU
Remodulin 1 mg/ml, oplossing voor infusie	FR/H/0278/001	1648/05100103	FERRER INTERNACIONAL, S.A.	LU
Remodulin 2,5 mg/ml, oplossing voor infusie	FR/H/0278/002	1648/05100104	FERRER INTERNACIONAL, S.A.	LU
Remodulin 5 mg/ml, solution pour perfusion	FR/H/0278/003	1648/05100105	FERRER INTERNACIONAL, S.A.	LU
Remodulin 10 mg/ml, solution pour perfusion	FR/H/0278/004	1648/05100106	FERRER INTERNACIONAL, S.A.	LU
Remodulin 5 mg/ml, oplossing voor infusie	FR/H/0278/003	1648/05100105	FERRER INTERNACIONAL, S.A.	LU
Remodulin 10 mg/ml, oplossing voor infusie	FR/H/0278/004	1648/05100106	FERRER INTERNACIONAL, S.A.	LU
REMOTULIN, 1 mg/ml, roztwór do infuzji	FR/H/0278/001	12835	FERRER INTERNACIONAL, S.A.	PL
REMOTULIN, 2,5 mg/ml, roztwór do infuzji	FR/H/0278/002	12836	FERRER INTERNACIONAL, S.A.	PL
REMOTULIN, 5 mg/ml, roztwór do infuzji	FR/H/0278/003	12837	FERRER INTERNACIONAL, S.A.	PL
REMOTULIN, 10 mg/ml, roztwór, do infuzji	FR/H/0278/004	12838	FERRER INTERNACIONAL, S.A.	PL
REMOTULIN 1 mg/ml soluzione per infusione	FR/H/0278/001	037057015	FERRER INTERNACIONAL, S.A.	IT
REMOTULIN 2,5 mg/ml soluzione per infusione	FR/H/0278/001	037057027	FERRER INTERNACIONAL, S.A.	IT
REMOTULIN 5 mg/ml soluzione per infusione	FR/H/0278/003	037057039	FERRER INTERNACIONAL, S.A.	IT
REMOTULIN 10 mg/ml soluzione per infusione	FR/H/0278/004	037057041	FERRER INTERNACIONAL, S.A.	IT
REMOTULIN 1 mg/ml raztopina za infundiranje	FR/H/0278/001	H/08/01338/001	FERRER INTERNACIONAL, S.A.	SI
REMOTULIN 2,5 mg/ml	FR/H/0278/002	H/08/01338/002	FERRER INTERNACIONAL,	SI

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
raztopina za infundiranje			S.A.	
REMODULIN 5 mg/ml raztopina za infundiranje	FR/H/0278/003	H/08/01338/003	FERRER INTERNACIONAL, S.A.	SI
REMODULIN 10 mg/ml raztopina za infundiranje	FR/H/0278/004	H/08/01338/004	FERRER INTERNACIONAL, S.A.	SI
REMODULIN 1 mg/ml, Infusionslösung	FR/H/0278/001	63142.00.00	FERRER INTERNACIONAL, S.A.	DE
REMODULIN 2.5 mg/ml, Infusionslösung	FR/H/0278/002	63143.00.00	FERRER INTERNACIONAL, S.A.	DE
REMODULIN 5 mg/ml, Infusionslösung	FR/H/0278/003	63144.00.00	FERRER INTERNACIONAL, S.A.	DE
REMODULIN 10 mg/ml, Infusionslösung	FR/H/0278/004	63145.00.00	FERRER INTERNACIONAL, S.A.	DE
REMODULIN 1 mg/ml innrennslyf, lausn	FR/H/0278/001	IS/1/05/035/01	FERRER INTERNACIONAL, S.A.	IS
REMODULIN 2,5 mg/ml innrennslyf, lausn	FR/H/0278/002	IS/1/05/035/02	FERRER INTERNACIONAL, S.A.	IS
REMODULIN 5 mg/ml innrennslyf, lausn	FR/H/0278/003	IS/1/05/035/03	FERRER INTERNACIONAL, S.A.	IS
REMODULIN 10 mg/ml innrennslyf, lausn	FR/H/0278/004	IS/1/05/035/04	FERRER INTERNACIONAL, S.A.	IS
REMODULIN, 1 mg/ml διάλυμα για έγχυση	FR/H/0278/001	20272	FERRER INTERNACIONAL, S.A.	CY
REMODULIN, 2,5 mg/ml διάλυμα για έγχυση	FR/H/0278/002	20274	FERRER INTERNACIONAL, S.A.	CY
REMODULIN, 5 mg/ml διάλυμα για έγχυση	FR/H/0278/003	20274	FERRER INTERNACIONAL, S.A.	CY
REMODULIN, 10 mg/ml διάλυμα για έγχυση	FR/H/0278/004	20275	FERRER INTERNACIONAL, S.A.	CY