



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6 July 2017
EMA/419279/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: treprostinil

Procedure no.: PSUSA/00003013/201611



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, solution pour perfusion	FR/H/0278/001	BE296362	UNITED THERAPEUTICS EUROPE LIMITED	BE
Remodulin 5 mg/ml, solution pour perfusion	FR/H/0278/003	BE296387	UNITED THERAPEUTICS EUROPE LIMITED	BE
Remodulin 10 mg/ml, solution pour perfusion	FR/H/0278/004	BE296396	UNITED THERAPEUTICS EUROPE LIMITED	BE
Remodulin 1 mg/ml, oplossing voor infusie	FR/H/0278/001	BE296362	UNITED THERAPEUTICS EUROPE LIMITED	BE
Remodulin 5 mg/ml, oplossing voor infusie	FR/H/0278/003	BE296387	UNITED THERAPEUTICS EUROPE LIMITED	BE
Remodulin 10 mg/ml, oplossing voor infusie	FR/H/0278/004	BE296396	UNITED THERAPEUTICS EUROPE LIMITED	BE
Remodulin 2,5 mg/ml, oplossing voor infusie	FR/H/0278/002	BE296371	UNITED THERAPEUTICS EUROPE LIMITED	BE
REMODYLIN, 1 mg/ml infusioonilohus	FR/H/0278/001	504705	UNITED THERAPEUTICS EUROPE LIMITED	EE
REMODYLIN, 2,5 mg/ml infusioonilohus	FR/H/0278/002	504505	UNITED THERAPEUTICS EUROPE LIMITED	EE
REMODYLIN, 5 mg/ml infusioonilohus	FR/H/0278/003	504405	UNITED THERAPEUTICS EUROPE LIMITED	EE
REMODYLIN, 10 mg/ml infusioonilohus	FR/H/0278/004	504605	UNITED THERAPEUTICS EUROPE LIMITED	EE
Remodulin 2,5 mg/ml, solution pour perfusion	FR/H/0278/002	BE296371	UNITED THERAPEUTICS EUROPE LIMITED	BE
Remodulin 1 mg/ml oldatos infúzió	FR/H/0278/001	OGYI-T-20185/01	UNITED THERAPEUTICS EUROPE LIMITED	HU
Remodulin 2,5 mg/ml oldatos infúzió	FR/H/0278/002	OGYI-T-20185/02	UNITED THERAPEUTICS EUROPE LIMITED	HU
Remodulin 5 mg/ml	FR/H/0278/003	OGYI-T-20185/03	UNITED THERAPEUTICS	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
oldatos infúzió			EUROPE LIMITED	
Remodulin 10 mg/ml oldatos infúzió	FR/H/0278/004	OGYI-T-20185/04	UNITED THERAPEUTICS EUROPE LIMITED	HU
REMODULIN 1 mg/ml, oplossing voor infusie	FR/H/0278/001	RVG 32550	UNITED THERAPEUTICS EUROPE LIMITED	NL
REMODULIN 2,5 mg/ml, oplossing voor infusie	FR/H/0278/002	RVG 32551	UNITED THERAPEUTICS EUROPE LIMITED	NL
REMODULIN 5 mg/ml, oplossing voor infusie	FR/H/0278/003	RVG 32552	UNITED THERAPEUTICS EUROPE LIMITED	NL
REMODULIN 10 mg/ml, oplossing voor infusie	FR/H/0278/004	RVG 32553	UNITED THERAPEUTICS EUROPE LIMITED	NL
REMODULIN 1 mg/ml škidums infuzijam	FR/H/0278/001	07-0201	UNITED THERAPEUTICS EUROPE LIMITED	LV
REMODULIN 2,5 mg/ml škidums infuzijam	FR/H/0278/002	07-0202	UNITED THERAPEUTICS EUROPE LIMITED	LV
REMODULIN 5 mg/ml škidums infuzijam	FR/H/0278/003	07-0203	UNITED THERAPEUTICS EUROPE LIMITED	LV
REMODULIN 10 mg/ml škidums infuzijam	FR/H/0278/004	07-0204	UNITED THERAPEUTICS EUROPE LIMITED	LV
REMODULIN 1 mg/ml innrennsislyf, lausn	FR/H/0278/001	IS/1/05/035/01	UNITED THERAPEUTICS EUROPE LIMITED	IS
REMODULIN 5 mg/ml innrennsislyf, lausn	FR/H/0278/003	IS/1/05/035/03	UNITED THERAPEUTICS EUROPE LIMITED	IS
REMODULIN 2,5 mg/ml innrennsislyf, lausn	FR/H/0278/002	IS/1/05/035/02	UNITED THERAPEUTICS EUROPE LIMITED	IS
REMODULIN 10 mg/ml innrennsislyf, lausn	FR/H/0278/004	IS/1/05/035/04	UNITED THERAPEUTICS EUROPE LIMITED	IS

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REMODULIN 1 mg/ml soluzione per infusione	FR/H/0278/001	037057015	UNITED THERAPEUTICS EUROPE LIMITED	IT
REMODULIN 2.5 mg/ml soluzione per infusione	FR/H/0278/002	037057027	UNITED THERAPEUTICS EUROPE LIMITED	IT
REMODULIN 5 mg/ml soluzione per infusione	FR/H/0278/003	037057039	UNITED THERAPEUTICS EUROPE LIMITED	IT
REMODULIN 10 mg/ml soluzione per infusione	FR/H/0278/004	037057041	UNITED THERAPEUTICS EUROPE LIMITED	IT
Remodulin 1 mg/ml infusjonsvæske, oppløsning	FR/H/0278/001	05-3455	UNITED THERAPEUTICS EUROPE LIMITED	NO
Remodulin 2,5 mg/ml infusjonsvæske, oppløsning	FR/H/0278/002	05-3456	UNITED THERAPEUTICS EUROPE LIMITED	NO
Remodulin 5 mg/ml infusjonsvæske, oppløsning	FR/H/0278/003	05-3457	UNITED THERAPEUTICS EUROPE LIMITED	NO
Remodulin 10 mg/ml infusjonsvæske, oppløsning	FR/H/0278/004	05-3458	UNITED THERAPEUTICS EUROPE LIMITED	NO
REMODULIN 1 mg/ml infuzinis tirpalas	FR/H/0278/001	LT/1/07/0903/001	UNITED THERAPEUTICS EUROPE LIMITED	LT
REMODULIN 2,5 mg/ml infuzinis tirpalas	FR/H/0278/002	LT/1/07/0903/002	UNITED THERAPEUTICS EUROPE LIMITED	LT
REMODULIN 5 mg/ml infuzinis tirpalas	FR/H/0278/003	LT/1/07/0903/003	UNITED THERAPEUTICS EUROPE LIMITED	LT
REMODULIN 10 mg/ml infuzinis tirpalas	FR/H/0278/004	LT/1/07/0903/004	UNITED THERAPEUTICS EUROPE LIMITED	LT

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Remodulin 1 mg/ml, oplossing voor infusie	FR/H/0278/001	BE296362	UNITED THERAPEUTICS EUROPE LIMITED	LU
Remodulin 2,5 mg/ml, oplossing voor infusie	FR/H/0278/002	BE296371	UNITED THERAPEUTICS EUROPE LIMITED	LU
Remodulin 5 mg/ml, oplossing voor infusie	FR/H/0278/003	BE296387	UNITED THERAPEUTICS EUROPE LIMITED	LU
Remodulin 10 mg/ml, oplossing voor infusie	FR/H/0278/004	BE296396	UNITED THERAPEUTICS EUROPE LIMITED	LU
REMODYLIN 1 mg/ml, solution pour perfusion	FR/H/0278/001	BE296362	UNITED THERAPEUTICS EUROPE LIMITED	LU
REMODYLIN 2,5 mg/ml, solution pour perfusion	FR/H/0278/002	BE296371	UNITED THERAPEUTICS EUROPE LIMITED	LU
REMODYLIN 5 mg/ml, solution pour perfusion	FR/H/0278/003	BE296387	UNITED THERAPEUTICS EUROPE LIMITED	LU
REMODYLIN 10 mg/ml, solution pour perfusion	FR/H/0278/004	BE296396	UNITED THERAPEUTICS EUROPE LIMITED	LU
REMODYLIN 1 mg/ml Infusionslösung	FR/H/0278/001	1-26454	UNITED THERAPEUTICS EUROPE LIMITED	AT
REMODYLIN 2,5 mg/ml Infusionslösung	FR/H/0278/002	1-26521	UNITED THERAPEUTICS EUROPE LIMITED	AT
REMODYLIN 5 mg/ml Infusionslösung	FR/H/0278/003	1-26522	UNITED THERAPEUTICS EUROPE LIMITED	AT
REMODYLIN 10 mg/ml Infusionslösung	FR/H/0278/004	1-26523	UNITED THERAPEUTICS EUROPE LIMITED	AT
REMODYLIN 1 mg/ml, roztwór do infuzji	FR/H/0278/001	12835	UNITED THERAPEUTICS EUROPE LIMITED	PL
REMODYLIN, 2,5 mg/ml, roztwór do infuzji	FR/H/0278/002	12836	UNITED THERAPEUTICS EUROPE LIMITED	PL

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, roztwór do infuzji	FR/H/0278/003	12837	UNITED THERAPEUTICS EUROPE LIMITED	PL
REMODULIN 10 mg/ml, roztwór do infuzji	FR/H/0278/004	12838	UNITED THERAPEUTICS EUROPE LIMITED	PL
REMODULIN 1 mg/ml Infuzní roztok	FR/H/0278/001	83/340/05-C	UNITED THERAPEUTICS EUROPE LIMITED	CZ
REMODULIN 2,5 mg/ml Infuzní roztok	FR/H/0278/002	83/341/05-C	UNITED THERAPEUTICS EUROPE LIMITED	CZ
REMODULIN 5 mg/ml Infuzní roztok	FR/H/0278/003	83/342/05-C	UNITED THERAPEUTICS EUROPE LIMITED	CZ
REMODULIN 10 mg/ml Infuzní roztok	FR/H/0278/004	83/343/05-C	UNITED THERAPEUTICS EUROPE LIMITED	CZ
REMODULIN, 1 mg/ml διάλυμα για έγχυση	FR/H/0278/001	17005/14-3-06	UNITED THERAPEUTICS EUROPE LIMITED	GR
REMODULIN, 2,5 mg/ml διάλυμα για έγχυση	FR/H/0278/002	17006/14-3-06	UNITED THERAPEUTICS EUROPE LIMITED	GR
REMODULIN, 5 mg/ml διάλυμα για έγχυση	FR/H/0278/003	17007/14-3-06	UNITED THERAPEUTICS EUROPE LIMITED	GR
REMODULIN, 10 mg/ml διάλυμα για έγχυση	FR/H/0278/004	17009/14-3-06	UNITED THERAPEUTICS EUROPE LIMITED	GR
REMODULIN, 1 mg/ml διάλυμα για έγχυση	FR/H/0278/001	20272	UNITED THERAPEUTICS EUROPE LIMITED	CY
REMODULIN, 2,5 mg/ml διάλυμα για έγχυση	FR/H/0278/002	20273	UNITED THERAPEUTICS EUROPE LIMITED	CY
REMODULIN, 5 mg/ml διάλυμα για έγχυση	FR/H/0278/003	20274	UNITED THERAPEUTICS EUROPE LIMITED	CY
REMODULIN, 10 mg/ml διάλυμα για έγχυση	FR/H/0278/004	20275	UNITED THERAPEUTICS EUROPE LIMITED	CY

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Remodulin 1 mg/ml solução para perfusão	FR/H/0278/001	5683081	UNITED THERAPEUTICS EUROPE LIMITED	PT
Remodulin, 2,5 mg/ml solução para perfusão	FR/H/0278/002	5683180	UNITED THERAPEUTICS EUROPE LIMITED	PT
Remodulin 5 mg/ml solução para perfusão	FR/H/0278/003	5683289	UNITED THERAPEUTICS EUROPE LIMITED	PT
Remodulin 10 mg/ml solução para perfusão	FR/H/0278/004	5683388	UNITED THERAPEUTICS EUROPE LIMITED	PT
REMODULIN 1 mg/ml raztopina za infundiranje	FR/H/0278/001	H/08/01338/001	UNITED THERAPEUTICS EUROPE LIMITED	SI
REMODULIN 2,5 mg/ml raztopina za infundiranje	FR/H/0278/002	H/08/01338/002	UNITED THERAPEUTICS EUROPE LIMITED	SI
REMODULIN 5 mg/ml raztopina za infundiranje	FR/H/0278/003	H/08/01338/003	UNITED THERAPEUTICS EUROPE LIMITED	SI
REMODULIN 10 mg/ml raztopina za infundiranje	FR/H/0278/004	H/08/01338/004	UNITED THERAPEUTICS EUROPE LIMITED	SI
REMODULIN 1 mg/ml infusioneste, liuos	FR/H/0278/001	21101	UNITED THERAPEUTICS EUROPE LIMITED	FI
REMODULIN 2,5 mg/ml infusioneste, liuos	FR/H/0278/002	21103	UNITED THERAPEUTICS EUROPE LIMITED	FI
REMODULIN 5 mg/ml infusioneste, liuos	FR/H/0278/003	21104	UNITED THERAPEUTICS EUROPE LIMITED	FI
REMODULIN 10 mg/ml infusioneste, liuos	FR/H/0278/004	21102	UNITED THERAPEUTICS EUROPE LIMITED	FI
REMODULIN 1 mg/ml infusionsvätska, lösning	FR/H/0278/001	22464	UNITED THERAPEUTICS EUROPE LIMITED	SE
REMODULIN 2,5 mg/ml infusionsvätska, lösning	FR/H/0278/002	22465	UNITED THERAPEUTICS EUROPE LIMITED	SE

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 infusionsvätska, lösning	FR/H/0278/003	22466	UNITED THERAPEUTICS EUROPE LIMITED	SE
REMODULIN 10 mg/ml infusionsvätska, lösning	FR/H/0278/004	22467	UNITED THERAPEUTICS EUROPE LIMITED	SE
REMODULIN 1 mg/ml, Infusionslösung zur subkutanen Anwendung	FR/H/0278/001	63142.00.00	UNITED THERAPEUTICS EUROPE LIMITED	DE
REMODULIN 2.5 mg/ml, Infusionslösung zur subkutanen Anwendung	FR/H/0278/002	63143.00.00	UNITED THERAPEUTICS EUROPE LIMITED	DE
REMODULIN 5 mg/ml, Infusionslösung zur subkutanen Anwendung	FR/H/0278/003	63144.00.00	UNITED THERAPEUTICS EUROPE LIMITED	DE
REMODULIN 10 mg/ml, Infusionslösung zur subkutanen Anwendung	FR/H/0278/004	63145.00.00	UNITED THERAPEUTICS EUROPE LIMITED	DE
Remodulin, infusionsvæske, opløsning 1 mg/ml	FR/H/0278/001	37978	UNITED THERAPEUTICS EUROPE LIMITED	DK
Remodulin, infusionsvæske, opløsning 2,5 mg/ml	FR/H/0278/002	37979	UNITED THERAPEUTICS EUROPE LIMITED	DK
Remodulin, infusionsvæske, opløsning 5 mg/ml	FR/H/0278/003	37980	UNITED THERAPEUTICS EUROPE LIMITED	DK
Remodulin, infusionsvæske, opløsning 10 mg/ml	FR/H/0278/004	37981	UNITED THERAPEUTICS EUROPE LIMITED	DK

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REMODULIN 1 mg/ml infúzny roztok	FR/H/0278/001	16/0315/05-S	UNITED THERAPEUTICS EUROPE LIMITED	SK
REMODULIN 2,5 mg/ml infúzny roztok	FR/H/0278/002	16/0316/05-S	UNITED THERAPEUTICS EUROPE LIMITED	SK
REMODULIN 5 mg/ml infúzny roztok	FR/H/0278/003	16/0317/05-S	UNITED THERAPEUTICS EUROPE LIMITED	SK
REMODULIN 10 mg/ml infúzny roztok	FR/H/0278/004	16/0318/05-S	UNITED THERAPEUTICS EUROPE LIMITED	SK
Remodulin 1 mg/ml otopina za infuziju	not available	UP/I-530-09/13-02/172	UNITED THERAPEUTICS EUROPE LIMITED	HR
Remodulin 2,5 mg/ml otopina za infuziju	not available	UP/I-530-09/13-02/173	UNITED THERAPEUTICS EUROPE LIMITED	HR
Remodulin 5 mg/ml otopina za infuziju	not available	UP/I-530-09/13-02/174	UNITED THERAPEUTICS EUROPE LIMITED	HR
Remodulin 10 mg/ml otopina za infuziju	not available	UP/I-530-09/13-02/175	UNITED THERAPEUTICS EUROPE LIMITED	HR
REMODULIN 1 mg/ml, solution pour perfusion	FR/H/0278/001	368 161-5	UNITED THERAPEUTICS EUROPE LIMITED	FR
REMODULIN 2,5 mg/ml, solution pour perfusion	FR/H/0278/002	368 162-1	UNITED THERAPEUTICS EUROPE LIMITED	FR
REMODULIN 5 mg/ml, solution pour perfusion	FR/H/0278/003	368 163-8	UNITED THERAPEUTICS EUROPE LIMITED	FR
REMODULIN 10 mg/ml, solution pour perfusion	FR/H/0278/004	368 164-4	UNITED THERAPEUTICS EUROPE LIMITED	FR