



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 January 2017
EMA/169484/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: treprostinil

Procedure no.: PSUSA/00003013/201605

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Send a question via our website www.ema.europa.eu/contact

An agency of the European Union



| 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 |
| REMODULIN, 1 mg/ml infusioonilahas | FR/H/0278/001 | 504705 | UNITED THERAPEUTICS EUROPE LIMITED | EE |
| REMODULIN, 2,5 mg/ml infusioonilahas | FR/H/0278/002 | 504505 | UNITED THERAPEUTICS EUROPE LIMITED | EE |
| REMODULIN, 5 mg/ml infusioonilahas | FR/H/0278/003 | 504405 | UNITED THERAPEUTICS EUROPE LIMITED | EE |
| REMODULIN, 10 mg/ml infusioonilahas | FR/H/0278/004 | 504605 | UNITED THERAPEUTICS EUROPE LIMITED | EE |

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| 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 oldatos infúzió | FR/H/0278/003 | OGYI-T-20185/03 | UNITED THERAPEUTICS EUROPE LIMITED | HU |
| 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 |

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| REMODULIN 10 mg/ml škidums infuzijam | FR/H/0278/004 | 07-0204 | UNITED THERAPEUTICS EUROPE LIMITED | LV |
| REMODULIN 1 mg/ml innrennsliislyf, lausn | FR/H/0278/001 | IS/1/05/035/01 | UNITED THERAPEUTICS EUROPE LIMITED | IS |
| REMODULIN 5 mg/ml innrennsliislyf, lausn | FR/H/0278/003 | IS/1/05/035/03 | UNITED THERAPEUTICS EUROPE LIMITED | IS |
| REMODULIN 2,5 mg/ml innrennsliislyf, lausn | FR/H/0278/002 | IS/1/05/035/02 | UNITED THERAPEUTICS EUROPE LIMITED | IS |
| REMODULIN 10 mg/ml innrennsliislyf, lausn | FR/H/0278/004 | IS/1/05/035/04 | UNITED THERAPEUTICS EUROPE LIMITED | IS |
| 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 |

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| 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 |
| 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 |
| REMODULIN 1 mg/ml, solution pour perfusion | FR/H/0278/001 | BE296362 | UNITED THERAPEUTICS EUROPE LIMITED | LU |

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

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| 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 |
| Remodulin 1 mg/ml solução para perfusão | FR/H/0278/001 | 5683081 | UNITED THERAPEUTICS EUROPE LIMITED | PT |

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| 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 |

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| REMODULIN 2,5 mg/ml infusionsvätska, lösning | FR/H/0278/002 | 22465 | UNITED THERAPEUTICS EUROPE LIMITED | SE |
| 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 |

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| 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 |
| REMODULIN 1 mg/ml infúzný roztok | FR/H/0278/001 | 16/0315/05-S | UNITED THERAPEUTICS EUROPE LIMITED | SK |
| REMODULIN 2,5 mg/ml infúzný roztok | FR/H/0278/002 | 16/0316/05-S | UNITED THERAPEUTICS EUROPE LIMITED | SK |
| REMODULIN 5 mg/ml infúzný roztok | FR/H/0278/003 | 16/0317/05-S | UNITED THERAPEUTICS EUROPE LIMITED | SK |
| REMODULIN 10 mg/ml infúzný 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 |

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| 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 |