07 May 2026
EMADOC-1700519818-3153080
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): bivalirudin

EURD list No. PSUSA/00000421/202509

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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
Bivalirudin 250 mg powder for concentrate for solution for injection or infusion.	not available	PL 44853/0083	KENSINGTON PHARMA LTD	XI
Bivalirudin 250 mg powder for concentrate for solution for injection or infusion.	SE/H/1499/001	PL 44095/0035	REIG JOFRE UK LIMITED	XI
Bivalirudin Reig Jofre 250 mg pulver till koncentrat till injektions-/infusionsvätska, lösning.	SE/H/1499/001	52214	LABORATORIO REIG JOFRE, S.A.	SE
Bivalirudin Reig Jofre 250 mg pulver til koncentrat til injektionsvæske eller infusionsvæske, opløsning.	SE/H/1499/001	55214	LABORATORIO REIG JOFRE, S.A.	DK
Bivalirudin Reig Jofre 250 mg, kuiva-aine välikonsentraatiksi injektio-/infuusionestettä varten, liuos	SE/H/1499/001	32932	LABORATORIO REIG JOFRE, S.A.	FI
Bivalirudina Sala 250 mg polvo para concentrado para solución inyectable o para perfusión EFG.	SE/H/1499/001	80912	LABORATORIO REIG JOFRE, S.A.	ES
Bivalirudin Reig Jofre 250 mg pulver till koncentrat till injektions-/infusionsvätska, lösning	SE/H/1499/001	32932	LABORATORIO REIG JOFRE, S.A.	FI
Bivalirudin Accord 250 mg Pulver für ein Konzentrat zur	AT/H/0586/001	136968	ACCORD HEALTHCARE B.V.	AT

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Herstellung einer Injektions- oder Infusionslösung				
Bivalirudina Accord 250 mg pó para concentrado para solução injetável ou para perfusão.	AT/H/0586/001	5684342	ACCORD HEALTHCARE S.L.U.	PT
Bivalirudina Accord 250 mg pó para concentrado para solução injetável ou para perfusão.	AT/H/0586/001	5685359	ACCORD HEALTHCARE S.L.U.	PT
Bivalirudina Accord 250 mg pó para concentrado para solução injetável ou para perfusão.	AT/H/0586/001	5685367	ACCORD HEALTHCARE S.L.U.	PT
Bivalirudine Accord 250 mg poeder voor concentraat voor oplossing voor injectie of infusie	AT/H/0586/001	RVG 116622	ACCORD HEALTHCARE B.V.	NL
Bivalirudin Accord Healthcare 250 mg poeder voor concentraat voor oplossing voor injectie of infusie	AT/H/0586/001	BE 501111	ACCORD HEALTHCARE B.V.	BE
Bivalirudin Accord Healthcare 250 mg poudre pour solution à diluer pour solution injectable ou pour perfusion.	AT/H/0586/001	BE 501111	ACCORD HEALTHCARE B.V.	BE
Bivalirudin Accord 250 mg prašek za koncentrat za raztopino za injiciranje/infundiranje	AT/H/0586/001	H/16/02228/001	ACCORD HEALTHCARE POLSKA SP. Z O.O.	SI
Bivalirudin Accord 250	AT/H/0586/001	H/16/02228/002	ACCORD HEALTHCARE	SI

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mg prašek za koncentrat za raztopino za injiciranje/infundiranje			POLSKA SP. Z O.O.	
Bivalirudin Accord 250 mg prašek za koncentrat za raztopino za injiciranje/infundiranje	AT/H/0586/001	H/16/02228/003	ACCORD HEALTHCARE POLSKA SP. Z O.O.	SI
Bivalirudina Accord 250 mg, polvere per concentrato per soluzione per iniezione/infusione.	AT/H/0586/001	044084010	ACCORD HEALTHCARE S.L.U.	IT
Bivalirudina Accord 250 mg, polvere per concentrato per soluzione per iniezione/infusione.	AT/H/0586/001	044084022	ACCORD HEALTHCARE S.L.U.	IT
Bivalirudina Accord 250 mg, polvere per concentrato per soluzione per iniezione/infusione	AT/H/0586/001	044084034	ACCORD HEALTHCARE S.L.U.	IT
Biwalirudyna Accord, 250 mg, proszek do sporządzania koncentratu roztworu do wstrzykiwań / do infuzji.	AT/H/0586/001	23487	ACCORD HEALTHCARE POLSKA SP. Z O.O.	PL
Bivalirudin Accord 250 mg Pulver zur Herstellung eines Konzentrates für eine Injektions- oder Infusionslösung	AT/H/0586/001	94238.00.00	ACCORD HEALTHCARE B.V.	DE
BIVALIRUDINE ACCORD 250 mg, poudre pour solution à diluer pour	AT/H/0586/001	34009 550 486 6 4	ACCORD HEALTHCARE FRANCE SAS	FR

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solution injectable/pour perfusion				
BIVALIRUDINE ACCORD 250 mg, poudre pour solution à diluer pour solution injectable/pour perfusion	AT/H/0586/001	34009 550 486 7 1	ACCORD HEALTHCARE FRANCE SAS	FR
BIVALIRUDINE ACCORD 250 mg, poudre pour solution à diluer pour solution injectable/pour perfusion	AT/H/0586/001	34009 550 486 8 8	ACCORD HEALTHCARE FRANCE SAS	FR
Bivalirudin 250 mg powder for concentrate for solution for injection or infusion	AT/H/0586/001	PL 20075/0438	ACCORD HEALTHCARE LIMITED	XI
Bivalirudin Hikma 250 mg poeder voor concentraat voor oplossing voor injectie/infusie	NL/H/4677/001	BE664616	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	BE
Bivalirudin Hikma 250 mg poudre pour solution à diluer pour solution injectable/pour perfusion.	NL/H/4677/001	BE664616	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	BE
Bivalirudin Hikma 250 mg Pulver für ein Konzentrat zur Herstellung einer Injektions-/Infusionslösung	NL/H/4677/001	BE664616	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	BE
Bivalirudina Hikma 250 mg pó para concentrado para solução injetável ou para perfusão.	NL/H/4677/001	5911409	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	PT

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BIVALIRUDINE HIKMA 250 mg, poudre pour solution à diluer pour solution injectable/pour perfusion	NL/H/4677/001	34009 551 103 5 4	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	FR
Bivalirudina Hikma 250 mg de polvo para concentrado para solución inyectable y para perfusión EFG	NL/H/4677/001	90.576	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	ES
Bivalirudina Hikma 250 mg polvere per concentrato per soluzione iniettabile/infusione.	NL/H/4677/001	051795019	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	IT