



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6 May 2021
EMA/246488/2021
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance(s): bivalirudin

Procedure No.: PSUSA/00000421/202009



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
Bivalirudine ADOH 250 mg poeder voor concentraat voor oplossing voor injectie/infusie	NL/H/4677/001	RVG 124387	ADOH B.V.	NL
Bivalirudin ADOH 250 mg Pulver für ein Konzentrat zur Herstellung einer Injektions-/Infusionslösung	NL/H/4677/001	2203661.00.00	ADOH B.V.	DE
Bivalirudin 250 mg powder for concentrate for solution for injection or infusion	SE/H/1499/001	PL 25174/0027	LABORATORIO REIG JOFRE, S.A.	XI
Bivalidrudin Reig Jofre 250 mg stofn fyrir stungulyfs-/innrennslisþykkni, lausn.	SE/H/1499/001	IS/1/15/143/01	LABORATORIO REIG JOFRE, S.A.	IS
Bivalirudin Reig Jofre 250 mg pulver till konzentrat till injektions-/infusionsvätska, lösning.	SE/H/1499/001	52214	LABORATORIO REIG JOFRE, S.A.	SE
Bivalirudin Reig Jofre 250 mg pulver til konzentrat 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-/infusionestettä 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 konzentrat till injektions-/infusionsvätska, lösning	SE/H/1499/001	32932	LABORATORIO REIG JOFRE, S.A.	FI
Bivalirudin 250 mg powder for concentrate for solution for injection or infusion	AT/H/0586/001	PL 20075/0438	ACCORD HEALTHCARE LIMITED	UK
Bivalirudin Accord 250 mg Pulver für ein Konzentrat zur Herstellung einer Injektions- oder Infusionslösung	AT/H/0586/001	136968	ACCORD HEALTHCARE B.V.	AT
Bivalirudina Accord 250 mg pó para concentrado para solução injetável ou para perfusão.	AT/H/0586/001	5685342	ACCORD HEALTHCARE LIMITED	PT
Bivalirudina Accord 250 mg pó para concentrado	AT/H/0586/001	5685359	ACCORD HEALTHCARE	PT

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
para solução injetável ou para perfusão.			LIMITED	
Bivalirudina Accord 250 mg pó para concentrado para solução injetável ou para perfusão.	AT/H/0586/001	5685367	ACCORD HEALTHCARE LIMITED	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 250 mg, kuiva-aine välikonsentraatiksi injektio-/infusionestettä varten, liuos	AT/H/0586/001	32946	ACCORD HEALTHCARE B.V.	FI
Bivalirudin Accord 250 mg pulver till koncentrat till injektions-/infusionsvätska, lösning.	AT/H/0586/001	52269	ACCORD HEALTHCARE B.V.	SE
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 mg prašek za koncentrat za raztopino za injiciranje/infundiranje	AT/H/0586/001	H/16/02228/002	ACCORD HEALTHCARE POLSKA SP. Z O.O.	SI
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 iniettabile o per infusione.	AT/H/0586/001	044084010	ACCORD HEALTHCARE S.L.U.	IT
Bivalirudina Accord 250 mg, polvere per concentrato per soluzione iniettabile o per infusione.	AT/H/0586/001	044084022	ACCORD HEALTHCARE S.L.U.	IT

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Bivalirudina Accord 250 mg, polvere per concentrato per soluzione iniettabile o per 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
Bivalirudina Accord 250 mg de polvo para concentrado para solución inyectable y para perfusión EFG	AT/H/0586/001	81564	ACCORD HEALTHCARE S.L.U.	ES
BIVALIRUDINE ACCORD 250 mg, poudre pour solution à diluer pour solution injectable/pour perfusion	AT/H/0586/001	34009 550 486 6 4	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 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