

Amsterdam, 11 November 2021
EMA/656136/2021
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: argatroban

Procedure no.: PSUSA/ 00009057/202101

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
ARGANOVA 1 mg/mL, solution pour perfusion	SE/H/0483/004	NL51060	mitsubishi tanabe pharma gmbh	FR
Arganova 100 mg/ml concentrado para solución para perfusión.	SE/H/0483/001	74548	mitsubishi tanabe pharma gmbh	ES
ARGANOVA 100 mg/mL, solution à diluer pour perfusion en multidose	SE/H/0483/002	NL43524	mitsubishi tanabe pharma gmbh	FR
Arganova Multidose 100 mg/ml concentraat voor oplossing voor infusie.	SE/H/0483/002	RVG 107000	mitsubishi tanabe pharma gmbh	NL
Argatra 1 mg/ml Infusionslösung	SE/H/0483/004	94283.00.00	mitsubishi tanabe pharma gmbh	DE
Argatra Multidose 100 mg/ml Konzentrat zur Herstellung einer Infusionslösung.	SE/H/0483/002	81323.00.00	mitsubishi tanabe pharma gmbh	DE
Argatra® 1 mg/ml Infusionslösung	SE/H/0483/004	137129	mitsubishi tanabe pharma gmbh	AT
Argatra® Multidose 100 mg/ml Konzentrat zur Herstellung einer Infusionslösung	SE/H/0483/002	1-29763	mitsubishi tanabe pharma gmbh	AT

Argatroban 1 mg/ml Solution for Infusion.	DE/H/5959/001	PL 20075/0486	ACCORD HEALTHCARE LIMITED	XI
Argatroban Accord 1 mg/ml Infusionslösung	DE/H/5959/001	137725	ACCORD HEALTHCARE B.V.	AT
Argatroban Accord 1 mg/ml Infusionslösung	DE/H/5959/001	96950.00.00	ACCORD HEALTHCARE B.V.	DE
ARGATROBAN ACCORD 1 mg/mL, solution pour perfusion	DE/H/5959/001	34009 550 348 9 6	ACCORD HEALTHCARE FRANCE SAS	FR
ARGATROBAN ACCORD 1 mg/mL, solution pour perfusion	DE/H/5959/001	34009 550 349 0 2	ACCORD HEALTHCARE FRANCE SAS	FR
ARGATROBAN ACCORD 1 mg/mL, solution pour perfusion	DE/H/5959/001	34009 300 997 9 7	ACCORD HEALTHCARE FRANCE SAS	FR
Novastan 100 mg/ml infuusiokonsentraatti, liuosta varten.	SE/H/0483/002	28469	MITSUBISHI TANABE PHARMA GMBH	FI
Novastan 100 mg/ml konsentrat til infusjonsvæske, oppløsning.	SE/H/483/01-02/IB/52	05-3354	MITSUBISHI TANABE PHARMA GMBH	NO
Novastan 100 mg/ml, concentrato per soluzione per infusione.	SE/H/0483/001	037482015	MITSUBISHI TANABE PHARMA GMBH	IT

Novastan 100 mg/ml, concentrato per soluzione per infusione.	SE/H/0483/001	037482015	mitsubishi tanabe pharma gmbh	IT
Novastan Multidos 100 mg/ml koncentrat till infusionsvätska, lösning	SE/H/0483/002	26763	mitsubishi tanabe pharma gmbh	SE
Novastan, 1 mg/ml infusionsvätska, lösning.	SE/H/0483/004	52237	mitsubishi tanabe pharma gmbh	SE
Novastan, 100 mg/ml koncentrat till infusionsvätska, lösning.	SE/H/0483/001	19239	mitsubishi tanabe pharma gmbh	SE
Novastan, koncentrat til infusionsvæske, opløsning	SE/H/0483/001	37824	mitsubishi tanabe pharma gmbh	DK