



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

04 October 2018
EMA/701236/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: argatroban

Procedure no.: PSUSA/00009057/201801



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
Novastan 100 mg/ml, concentrato per soluzione per infusione	SE/H/0483/001	037482015	mitsubishi tanabe pharma europe ltd.	IT
Novastan, 100 mg/ml koncentrat till infusionsvätska, lösning	SE/H/0483/001	19239	mitsubishi tanabe pharma europe ltd.	SE
Novastan 100 mg/ml, concentrato per soluzione per infusione	SE/H/0483/001	037482027	mitsubishi tanabe pharma europe ltd.	IT
Arganova 100 mg/ml concentrado para solución para perfusión	SE/H/0483/001	74548	mitsubishi tanabe pharma europe ltd.	ES
Novastan 100 mg/ml konsentrat til infusjonsvæske, oppløsning	SE/H/0483/001	05-3354	mitsubishi tanabe pharma europe ltd.	NO
Novastan 100 mg koncentrat til infusionsvæske, opløsning	SE/H/0483/001	37824	mitsubishi tanabe pharma europe ltd.	DK
ARGANOVA 100 mg/ml, solution à diluer pour perfusion	SE/H/0483/001	34009 416 968 7 9	mitsubishi tanabe pharma europe ltd.	FR
ARGANOVA 100 mg/ml, solution à diluer pour perfusion	SE/H/0483/001	34009 416 969 3 0	mitsubishi tanabe pharma europe ltd.	FR
Exembol 1 mg/ml Solution for Infusion	SE/H/0483/004	PL 20012/0011	mitsubishi tanabe pharma europe ltd.	UK

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
Argatra® 1 mg/ml Infusionslösung	SE/H/0483/004	137129	MITSUBISHI TANABE PHARMA EUROPE LTD.	AT
Novastan, 1 mg/ml infusionsvätska, lösning	SE/H/0483/004	52237	MITSUBISHI TANABE PHARMA EUROPE LTD.	SE
Argatra 1 mg/ml Infusionslösung	SE/H/0483/004	94283.00.00	MITSUBISHI TANABE PHARMA EUROPE LTD.	DE
Exembol Multidose 100 mg/ml concentrate for solution for infusion	SE/H/0483/002	PL 20012/0009	MITSUBISHI TANABE PHARMA EUROPE LTD.	UK
ARGANOVA 100 mg/mL, solution à diluer pour perfusion en multidose	SE/H/0483/002	NL 43524	MITSUBISHI TANABE PHARMA EUROPE LTD.	FR
Novastan Multidos 100 mg/ml koncentrat till infusionsvätska, lösning	SE/H/0483/002	26763	MITSUBISHI TANABE PHARMA EUROPE LTD.	SE
Argatra® Multidose 100 mg/ml Konzentrat zur Herstellung einer Infusionslösung	SE/H/0483/002	1-29763	MITSUBISHI TANABE PHARMA EUROPE LTD.	AT
Argatra Multidose 100 mg/ml Konzentrat zur Herstellung einer Infusionslösung	SE/H/0483/002	81323.00.00	MITSUBISHI TANABE PHARMA EUROPE LTD.	DE

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
Novastan 100 mg/ml infuusiokonsentraatti, liuosta varten	SE/H/0483/002	28469	MITSUBISHI TANABE PHARMA EUROPE LTD.	FI
Arganova Multidose 100 mg/ml concentraat voor oplossing voor infusie	SE/H/0483/002	RVG 107000	MITSUBISHI TANABE PHARMA EUROPE LTD.	NL
Argatroban 1 mg/ml Solution for Infusion	UK/H/6275/001	PL 20075/0486	ACCORD HEALTHCARE LIMITED	UK
Argatroban Accord 1 mg/ml Infusionslösung	UK/H/6275/001	137725	ACCORD HEALTHCARE LIMITED	AT
ARGATROBAN ACCORD 1 mg/mL, solution pour perfusion	UK/H/6275/001	34009 550 348 9 6	ACCORD HEALTHCARE FRANCE SAS	FR
ARGATROBAN ACCORD 1 mg/mL, solution pour perfusion	UK/H/6275/001	34009 550 349 0 2	ACCORD HEALTHCARE FRANCE SAS	FR
ARGATROBAN ACCORD 1 mg/mL, solution pour perfusion	UK/H/6275/001	34009 300 997 9 7	ACCORD HEALTHCARE FRANCE SAS	FR
Argatroban Accord 1 mg/ml Infusionslösung	UK/H/6275/001	96950.00.00	ACCORD HEALTHCARE LIMITED	DE