



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 October 2020
EMA/494419/2020
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: labetalol

Procedure no.: PSUSA/00001814/202002



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
Trandate® 50 mg film-coated tablets	not available	PL 36301/0013	RPH PHARMACEUTICALS AB	UK
TRANDATE 100 mg comprimés pelliculés	not available	2008029685	ASPEN PHARMA TRADING LIMITED	LU
TRANDATE 200 mg comprimés pelliculés	not available	2008029686	ASPEN PHARMA TRADING LIMITED	LU
TRANDATE 200 mg Filmdabletten	not available	2008029686	ASPEN PHARMA TRADING LIMITED	LU
TRANDATE 100 mg Filmdabletten	not available	2008029685	ASPEN PHARMA TRADING LIMITED	LU
Trandate 5 mg/ml solución inyectable	not available	55.318	KERN PHARMA, S.L.	ES

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
Trandate 100 mg filmdragerade tabletter	not available	9732	ASPEN PHARMA TRADING LIMITED	SE
Trandate 200 mg filmdragerade tabletter	not available	9733	ASPEN PHARMA TRADING LIMITED	SE
TRANDATE 5 mg/ml, solution injectable	not available	552 496-6	ASPEN PHARMA TRADING LIMITED	FR
TRANDATE 5 mg/ml, solution injectable	not available	552 494-3	ASPEN PHARMA TRADING LIMITED	FR
Trandate Injectie, oplossing voor injectie 5 mg/ml	not available	RVG 07879	ASPEN PHARMA TRADING LIMITED	NL
TRANDATE 5 mg/ml solution injectable	not available	2008029684	ASPEN PHARMA TRADING LIMITED	LU

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
TRANDATE 5 mg/ml Injektionslösung	not available	2008029684	ASPEN PHARMA TRADING LIMITED	LU
Trandate, injektionsvæske, opløsning	not available	7000	ASPEN PHARMA TRADING LIMITED	DK
Trandate 100mg Film-Coated Tablets.	not available	PA1638/006/002	RPH PHARMACEUTICALS AB	IE
TRANDATE 200 mg Filmdabletten Labetalol- HCl	not available	BE 111045	ASPEN PHARMA TRADING LIMITED	BE
TRANDATE 100 mg Filmdabletten	not available	BE 111054	ASPEN PHARMA TRADING LIMITED	BE
TRANDATE 100 mg comprimés pelliculés	not available	BE 111054	ASPEN PHARMA TRADING LIMITED	BE

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
TRANDATE 100 mg filmomhulde tabletten	not available	BE 111054	ASPEN PHARMA TRADING LIMITED	BE
TRANDATE 200 mg comprimés pelliculés	not available	BE 111045	ASPEN PHARMA TRADING LIMITED	BE
TRANDATE 200 mg filmomhulde tabletten	not available	BE 111045	ASPEN PHARMA TRADING LIMITED	BE
Trandate® 100 mg film-coated tablets	not available	PL 36301/0014	RPH PHARMACEUTICALS AB	UK
Trandate 100 mg compresse rivestite con film	not available	023578014	TEOFARMA S.R.L.	IT
Trandate 200mg Film-coated Tablets.	not available	PA1638/006/003	RPH PHARMACEUTICALS AB	IE

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
Labetalol Pharmakern 5 mg/ml solução injetável	not available	5767504	PHARMAKERN PORTUGAL – PRODUTOS FARMACÊUTICOS, SOCIEDADE UNIPESSOAL, LDA.	PT
Trandate 200 mg comprimidos recubiertos	not available	54.528	KERN PHARMA, S.L.	ES
Trandate 100 mg comprimidos recubiertos	not available	54.527	KERN PHARMA, S.L.	ES
Trandate 5 mg/ml injektionsvätska, lösning	not available	9731	ASPEN PHARMA TRADING LIMITED	SE
Trandate, 100 mg õhukese polümeerikattega tabletid	not available	107595	ASPEN PHARMA TRADING LIMITED	EE
Trandate filmdrasjerte tabletter 100 mg	not available	6720	ASPEN PHARMA TRADING LIMITED	NO

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
Trandate filmdrasjerte tabletter 200 mg	not available	6721	ASPEN PHARMA TRADING LIMITED	NO
Trandate 100 mg- Ampullen	not available	17082	ASPEN PHARMA TRADING LIMITED	AT
Trandate 5mg/ml Solution for Injection	not available	PA1638/006/001	RPH PHARMACEUTICALS AB	IE
Labetalol Tablets BP 200mg	not available	PL 04416/0083	SANDOZ LTD	UK
Labetalol Tablets BP 100mg	not available	PL 04416/0082	SANDOZ 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
Labetalol Tablets BP 400mg	not available	PL 04416/0084	SANDOZ LTD	UK
Trandate 5 mg/ml stungulyf, lausn	not available	843368	ASPEN PHARMA TRADING LIMITED	IS
Trandate injeksjonsvæske, oppløsning 5 mg/ml	not available	6719	ASPEN PHARMA TRADING LIMITED	NO
Trandate® 200 mg film-coated tablets	not available	PL 36301/0015	RPH PHARMACEUTICALS AB	UK
TRANDATE 200 mg, comprimé pelliculé	not available	374 823-6	ASPEN PHARMA TRADING LIMITED	FR
TRANDATE 200 mg, comprimé pelliculé	not available	322 652-6	ASPEN PHARMA TRADING LIMITED	FR

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
Trandate	not available	6999	ASPEN PHARMA TRADING LIMITED	DK
Trandate, injektionsvæske, opløsning	not available	7000	ASPEN PHARMA TRADING LIMITED	DK
TRANDATE 5 mg/ml Injektionslösung Labetalol-HCl	not available	BE 114843	ASPEN PHARMA TRADING LIMITED	BE
TRANDATE 5 mg/ml solution injectable	not available	BE 114843	ASPEN PHARMA TRADING LIMITED	BE
TRANDATE 5 mg/ml oplossing voor injectie	not available	BE 114843	ASPEN PHARMA TRADING LIMITED	BE
TRANDATE INJECTION, 5 mg/ml süstelahus	not available	107895	ASPEN PHARMA TRADING LIMITED	EE

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
Trandate 5mg/ml solution for injection	not available	PL 36301/0053	RPH PHARMACEUTICALS AB	UK
Trandate 100 mg filmuhúðaðar töflur	not available	722060	ASPEN PHARMA TRADING LIMITED	IS
Trandate 200 mg filmuhúðaðar töflur	not available	802562	ASPEN PHARMA TRADING LIMITED	IS
Trandate® 400 mg film-coated tablets	not available	PL 36301/0016	RPH PHARMACEUTICALS AB	UK
TRANDATE	not available	MZDR 20273/2018-4/FAR	ASPEN PHARMA TRADING LIMITED	CZ