



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 February 2019
EMA/130599/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: lidocaine hydrochloride / phenylephrine hydrochloride /
tropicamide

Procedure no.: PSUSA/00010390/201807



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
Fydrane 0.2 mg/ml + 3.1 mg/ml + 10 mg/ml solution for injection	DK/H/2439/001	PA 1107/012/001	LABORATOIRES THEA	IE
Fydrane 0.2 mg/ml + 3.1 mg/ml + 10 mg/ml solution for injection	DK/H/2439/001	PA 1107/012/001	LABORATOIRES THEA	IE
FYDRANE, 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml, solución inyectable	DK/H/2439/001	80177	LABORATOIRES THEA	ES
FYDRANE, 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml, solución inyectable	DK/H/2439/001	80177	LABORATOIRES THEA	ES
Mydane 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml injeksjonsvæske, oppløsning	DK/H/2439/001	14/10062	LABORATOIRES THEA	NO
Mydane 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml injeksjonsvæske, oppløsning	DK/H/2439/001	14/10062	LABORATOIRES THEA	NO
Mydrane 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml injekční roztok	DK/H/2439/001	64/399/15-C	LABORATOIRES THEA	CZ
Mydrane 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml injekční roztok	DK/H/2439/001	64/399/15-C	LABORATOIRES THEA	CZ
MYDRANE 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml injekčný roztok	DK/H/2439/001	64/0323/15-S	LABORATOIRES THEA	SK
MYDRANE 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml injekčný roztok	DK/H/2439/001	64/0323/15-S	LABORATOIRES THEA	SK
MYDRANE 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml injektioneste, liuos	DK/H/2439/001	32232	LABORATOIRES THEA	FI
MYDRANE 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml	DK/H/2439/001	32232	LABORATOIRES THEA	FI

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
injektioneste, liuos				
Mydrane 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml Injektionslösung	DK/H/2439/001	136615	LABORATOIRES THEA	AT
Mydrane 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml Injektionslösung	DK/H/2439/001	136615	LABORATOIRES THEA	AT
Mydrane 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml injektionsvätska, lösning	DK/H/2439/001	51088	LABORATOIRES THEA	SE
Mydrane 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml injektionsvätska, lösning	DK/H/2439/001	51088	LABORATOIRES THEA	SE
Mydrane 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml injektionsvätska, lösning	DK/H/2439/001	51088	LABORATOIRES THEA	SE
Mydrane 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml injektionsvätska, lösning	DK/H/2439/001	51088	LABORATOIRES THEA	SE
Mydrane 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml oplossing voor injectie	DK/H/2439/001	BE489680	LABORATOIRES THEA	BE
Mydrane 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml oplossing voor injectie	DK/H/2439/001	BE489680	LABORATOIRES THEA	BE
MYDRANE 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml oplossing voor injectie	DK/H/2439/001	RVG 115295	LABORATOIRES THEA	NL
MYDRANE 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml oplossing voor injectie	DK/H/2439/001	RVG 115295	LABORATOIRES THEA	NL
MYDRANE 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml otopina za injekciju	DK/H/2439/001	HR-H-561244487	LABORATOIRES THEA	HR
MYDRANE 0,2 mg/ml +	DK/H/2439/001	HR-H-561244487	LABORATOIRES THEA	HR

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
3,1 mg/ml + 10 mg/ml otopina za injekciju				
Mydrane 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml raztopina za injiciranje	DK/H/2439/001	H/17/02267/001-003	LABORATOIRES THEA	SI
Mydrane 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml raztopina za injiciranje	DK/H/2439/001	H/17/02267/001-003	LABORATOIRES THEA	SI
MYDRANE 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml solução injetável	DK/H/2439/001	5659370	LABORATOIRES THEA	PT
MYDRANE 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml solução injetável	DK/H/2439/001	5659404	LABORATOIRES THEA	PT
MYDRANE 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml solução injetável	DK/H/2439/001	5659370	LABORATOIRES THEA	PT
MYDRANE 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml solução injetável	DK/H/2439/001	5659404	LABORATOIRES THEA	PT
MYDRANE 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml soluție injectabilă.	DK/H/2439/001	8107/2015/01-03	LABORATOIRES THEA	RO
MYDRANE 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml soluție injectabilă.	DK/H/2439/001	8107/2015/01-03	LABORATOIRES THEA	RO
Mydrane 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml solution injectable	DK/H/2439/001	BE489680	LABORATOIRES THEA	BE
Mydrane 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml solution injectable	DK/H/2439/001	BE489680	LABORATOIRES THEA	BE
Mydrane 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml solution injectable	DK/H/2439/001	2016110311	LABORATOIRES THEA	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
Mydrane 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml solution injectable	DK/H/2439/001	2016110311	LABORATOIRES THEA	LU
MYDRANE 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml stungulyf, lausn	DK/H/2439/001	IS/1/15/094/01	LABORATOIRES THEA	IS
MYDRANE 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml stungulyf, lausn	DK/H/2439/001	IS/1/15/094/01	LABORATOIRES THEA	IS
MYDRANE 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml ενέσιμο διάλυμα.	DK/H/2439/001	022523	LABORATOIRES THEA	CY
MYDRANE 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml ενέσιμο διάλυμα.	DK/H/2439/001	022523	LABORATOIRES THEA	CY
MYDRANE 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml ενέσιμο διάλυμα.	DK/H/2439/001	36484/27-4-2016	LABORATOIRES THEA	GR
MYDRANE 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml ενέσιμο διάλυμα.	DK/H/2439/001	36484/27-4-2016	LABORATOIRES THEA	GR
MYDRANE 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml, solution injectable	DK/H/2439/001	34009 550 153 8 3	LABORATOIRES THEA	FR
MYDRANE 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml, solution injectable	DK/H/2439/001	34009 550 153 9 0	LABORATOIRES THEA	FR
MYDRANE 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml, solution injectable	DK/H/2439/001	34009 550 154 1 3	LABORATOIRES THEA	FR
MYDRANE 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml, solution injectable	DK/H/2439/001	34009 550 153 8 3	LABORATOIRES THEA	FR
MYDRANE 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml,	DK/H/2439/001	34009 550 153 9 0	LABORATOIRES THEA	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
solution injectable				
MYDRANE 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml, solution injectable	DK/H/2439/001	34009 550 154 1 3	LABORATOIRES THEA	FR
Mydrane 0.2 mg/ml + 3.1 mg/ml + 10 mg/ml solution for injection.	DK/H/2439/001	PL 20162/0022	LABORATOIRES THEA	UK
Mydrane 0.2 mg/ml + 3.1 mg/ml + 10 mg/ml solution for injection.	DK/H/2439/001	PL 20162/0022	LABORATOIRES THEA	UK
Mydrane, (0,2 mg + 3,1 mg + 10 mg)/ml, roztwór do wstrzykiwań	DK/H/2439/001	22899	LABORATOIRES THEA	PL
Mydrane, (0,2 mg + 3,1 mg + 10 mg)/ml, roztwór do wstrzykiwań	DK/H/2439/001	22899	LABORATOIRES THEA	PL
MYDRANE, 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml, soluzione iniettabile	DK/H/2439/001	043455043	LABORATOIRES THEA	IT
MYDRANE, 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml, soluzione iniettabile	DK/H/2439/001	043455056	LABORATOIRES THEA	IT
MYDRANE, 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml, soluzione iniettabile	DK/H/2439/001	043455068	LABORATOIRES THEA	IT
MYDRANE, 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml, soluzione iniettabile	DK/H/2439/001	043455043	LABORATOIRES THEA	IT
MYDRANE, 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml, soluzione iniettabile	DK/H/2439/001	043455056	LABORATOIRES THEA	IT
MYDRANE, 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml, soluzione iniettabile	DK/H/2439/001	043455068	LABORATOIRES THEA	IT
Mydrane, 0,2 mg/ml+	DK/H/2439/001	92056.00.00	LABORATOIRES THEA	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
3,1 mg/ml+ 10 mg/ml, Injektionslösung				
Mydrane, 0,2 mg/ml+ 3,1 mg/ml+ 10 mg/ml, Injektionslösung	DK/H/2439/001	92056.00.00	LABORATOIRES THEA	DE
Mydrane, injektionsvæske, opløsning	DK/H/2439/001	54107	LABORATOIRES THEA	DK
Mydrane, injektionsvæske, opløsning	DK/H/2439/001	54107	LABORATOIRES THEA	DK
МИДРАН 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml инжекционен разтвор.	DK/H/2439/001	20150368	LABORATOIRES THEA	BG
МИДРАН 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml инжекционен разтвор.	DK/H/2439/001	20150368	LABORATOIRES THEA	BG