



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 February 2022
EMA/64849/2022
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance(s): lidocaine hydrochloride / phenylephrine hydrochloride / tropicamide

Procedure No.: PSUSA/00010390/202107



Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number (if not available then insert not available)	National Authorisation Number of product in the member state	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, 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
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 injektioneste, liuos	DK/H/2439/001	32232	LABORATOIRES THEA	FI
Mydrane 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml Injektionslösung	DK/H/2439/001	BE489680	LABORATOIRES THEA	BE
Mydrane 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml injektionsvätska, lösning	DK/H/2439/001	32232	LABORATOIRES THEA	FI
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	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 + 3,1 mg/ml + 10 mg/ml raztopina za injiciranje	DK/H/2439/001	H/17/02267/001	LABORATOIRES THEA	SI
Mydrane 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml raztopina za injiciranje	DK/H/2439/001	H/17/02267/004	LABORATOIRES THEA	SI
Mydrane 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml raztopina za injiciranje	DK/H/2439/001	H/17/02267/005	LABORATOIRES THEA	SI
Mydrane 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml raztopina za injiciranje	DK/H/2439/001	H/17/02267/006	LABORATOIRES THEA	SI
Mydrane 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml raztopina za injiciranje	DK/H/2439/001	H/17/02267/002	LABORATOIRES THEA	SI
Mydrane 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml raztopina za injiciranje	DK/H/2439/001	H/17/02267/003	LABORATOIRES THEA	SI
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	5659404	LABORATOIRES THEA	PT
MYDRANE 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml soluție injectabilă	DK/H/2439/001	13579/2020/01	LABORATOIRES THEA	RO
MYDRANE 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml soluție injectabilă	DK/H/2439/001	13579/2020/02	LABORATOIRES THEA	RO
MYDRANE 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml soluție injectabilă	DK/H/2439/001	13579/2020/03	LABORATOIRES THEA	RO
MYDRANE 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml soluție injectabilă	DK/H/2439/001	13579/2020/04	LABORATOIRES THEA	RO
MYDRANE 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml soluție injectabilă	DK/H/2439/001	13579/2020/06	LABORATOIRES THEA	RO
MYDRANE 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml soluție injectabilă	DK/H/2439/001	13579/2020/05	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	2016110311	LABORATOIRES THEA	LU
Mydrane 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml stungulyf, lausn.	DK/H/2439/001	IS/1/15/093/01	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	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 550 554 8 8	LABORATOIRES THEA	FR
MYDRANE 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml, solution injectable	DK/H/2439/001	34009 550 555 0 1	LABORATOIRES THEA	FR
MYDRANE 0,2 mg/ml + 3,1 mg/ml + 10 mg/ml, solution injectable	DK/H/2439/001	34009 550 555 1 8	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	XI
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 Injektionslösung	DK/H/2439/001	2016110311	LABORATOIRES THEA	LU
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	92056.00.00	LABORATOIRES THEA	DE
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