



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

08 May 2025
EMA/PRAC/9837/2025
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): hexaminolevulinate hydrochloride

Procedure No. PSUSA/00001606/202409



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
Hexvix® 85 mg Pulver und Lösungsmittel zur Herstellung einer Lösung zur intravesikalen Anwendung	SE/H/0478/001	62171.00.00	PHOTOCURE ASA	AT
Hexvix® 85 mg poeder en oplosmiddel voor intravesicale oplossing	SE/H/0478/001	BE275134	PHOTOCURE ASA	BE
Hexvix® 85 mg Pulver und Lösungsmittel zur Herstellung einer intravesikalen Lösung	SE/H/0478/001	BE275134	PHOTOCURE ASA	BE
Hexvix 85 mg poudre et solvant pour solution intravésicale	SE/H/0478/001	BE275134	PHOTOCURE ASA	BE
Hexvix 85 mg prášek a rozpouštědlo pro intravezikální roztok	SE/H/0478/001	48/203/05-C	PHOTOCURE ASA	CZ
Hexvix® 85 mg Pulver und Lösungsmittel zur Herstellung einer Lösung zur intravesikalen Anwendung	SE/H/0478/001	62171.00.00	PHOTOCURE ASA	DE
Hexvix, pulver og solvens til intravesical opløsning	SE/H/0478/001	37422	PHOTOCURE ASA	DK
Hexvix, 85 mg intravesikaallahuse pulber ja lahusti	SE/H/0478/001	477805	PHOTOCURE ASA	EE
Hexvix 85 mg polvo y disolvente para solución intravesical.	SE/H/0478/001	66925	PHOTOCURE ASA	ES
Hexvix 85 mg jauhe ja liuotin liuosta varten, virtsarakkoon	SE/H/0478/001	20233	PHOTOCURE ASA	FI
HEXVIX 85 mg, poudre	SE/H/0478/001	34009 300 717 0 0	PHOTOCURE ASA	FR

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et solvant pour solution intravésicale				
HEXVIX 85 mg, poudre et solvant pour solution intravésicale	SE/H/0478/001	34009 300 717 1 7	PHOTOCURE ASA	FR
Hexvix 85 mg, κόνις και διαλύτης για ενδοκυστικό διάλυμα	SE/H/0478/01 MRP	91056/20/04-02-2021	PHOTOCURE ASA	GR
Hexvix 85 mg, κόνις και διαλύτης για ενδοκυστικό διάλυμα	SE/H/0478/01 MRP	91056/20/04-02-2021	PHOTOCURE ASA	GR
Hexvix 85 mg, κόνις και διαλύτης για ενδοκυστικό διάλυμα.	SE/H/0478/001	91056/20/04-02-2021	PHOTOCURE ASA	GR
Hexvix 85 mg por és oldószer intravezikális oldathoz	SE/H/0478/001	OGYI-T-20010/02	PHOTOCURE ASA	HU
Hexvix 85 mg por és oldószer intravezikális oldathoz	SE/H/0478/001	OGYI-T-20010/03	PHOTOCURE ASA	HU
Hexvix 85 mg, powder and solvent for intravesical solution.	SE/H/0478/001	PA1024/003/001	PHOTOCURE ASA	IE
Hexvix 85 mg, duft og leysir fyrir þvagblöðrulausn.	SE/H/0478/01	IS/1/05/004/01	PHOTOCURE ASA	IS
Hexvix 85 mg polvere e solvente per soluzione endovescicale	SE/H/0478/001	037598036	PHOTOCURE ASA	IT
Hexvix 85 mg polvere e solvente per soluzione endovescicale	SE/H/0478/001	037598048	PHOTOCURE ASA	IT
HEXVIX 85 mg milteliai ir tirpiklis šlapimo pūslės tirpalui	SE/H/0478/001	LT/1/06/0484/001	PHOTOCURE ASA	LT
HEXVIX 85 mg milteliai ir tirpiklis šlapimo pūslės tirpalui	SE/H/0478/001	LT/1/06/0484/002	PHOTOCURE ASA	LT
HEXVIX 85 mg pulveris	SE/H/0478/001	05-0332	PHOTOCURE ASA	LV

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un šķīdinātājs intravezikāli lietojama šķīduma pagatavošanai				
Hexvix 85 mg, poeder en oplosmiddel voor oplossing voor intravesicaal gebruik	SE/H/0478/001	RVG 31914	PHOTOCURE ASA	NL
Hexvix 85 mg pulver og væske til opløsning til intravesikal bruk	SE/H/478/001	04-3081	PHOTOCURE ASA	NO
Hexvix, 85 mg, proszek i rozpuszczalnik do sporządzania roztworu do pęcherza moczowego	SE/H/0478/001	11910	PHOTOCURE ASA	PL
Hexvix 85 mg pó e solvante para solução intravesical.	SE/H/0478/001	5589486	PHOTOCURE ASA	PT
Hexvix 85 mg pulver och vätska till intravesikal lösning.	SE/H/0478/001	19227	PHOTOCURE ASA	SE
Hexvix 85 mg prašek in vehikel za intravezikalno raztopino	SE/H/0478/001	H/06/00733/002	PHOTOCURE ASA	SI
Hexvix 85 mg prašek in vehikel za intravezikalno raztopino	SE/H/0478/001	H/06/00733/003	PHOTOCURE ASA	SI
Hexvix 85 mg, powder and solvent for intravesical solution	SE/H/0478/001	PL 18952/0004	PHOTOCURE ASA	XI