



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PRAC/380270/2018
Human Medicines Evaluation Division

List of nationally authorised products

Active substance(s): deoxycholic acid

Procedure No.: PSUSA/00010525/201710



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
Belkyra 10 mg/ml stungulyf, lausn	SE/H/1547/001	IS/1/16/071/01	ALLERGAN PHARMACEUTICAL INTERNATIONAL LIMITED	IS
Belkyra 10 mg/ml Injektionslösung	SE/H/1547/001	137169	ALLERGAN PHARMACEUTICAL INTERNATIONAL LIMITED	AT
Belkyra 10 mg/ml oldatos injekció	SE/H/1547/001	OGYI-T-23071/01	ALLERGAN PHARMACEUTICAL INTERNATIONAL LIMITED	HU
Belkyra, 10 mg/ml süstelahus	SE/H/1547/001	914216	ALLERGAN PHARMACEUTICAL INTERNATIONAL LIMITED	EE
Belkyra 10 mg/ml škidums injekcijam	SE/H/1547/001	16-0171	ALLERGAN PHARMACEUTICAL INTERNATIONAL LIMITED	LV
Belkyra 10 mg/ml injekcinis tirpalas	SE/H/1547/001	LT/1/16/3960/001	ALLERGAN PHARMACEUTICAL INTERNATIONAL LIMITED	LT
Belkyra 10 mg/ml soluție injectabilă	SE/H/1547/001	9314/2016/01	ALLERGAN PHARMACEUTICAL INTERNATIONAL LIMITED	RO
Белкира 10 mg/ml инжеクションен разтвор	SE/H/1547/001	20160303	ALLERGAN PHARMACEUTICAL INTERNATIONAL LIMITED	BG
Belkyra 10 mg/ml injektionsvätska, lösning	SE/H/1547/001	53380	ALLERGAN PHARMACEUTICAL INTERNATIONAL LIMITED	SE
Belkyra 10 mg/ml injeksjonsvæske, oppløsning	SE/H/1547/001	15-10850	ALLERGAN PHARMACEUTICAL INTERNATIONAL LIMITED	NO
Belkyra 10 mg/ml injekční roztok	SE/H/1547/001	87/406/16-C	ALLERGAN PHARMACEUTICAL INTERNATIONAL LIMITED	CZ
Belkyra 10 mg/ml solution for injection	SE/H/1547/001	MA1132/00201	ALLERGAN PHARMACEUTICAL INTERNATIONAL LIMITED	MT
BELKYRA 10 mg/ml injekčný roztok	SE/H/1547/001	46/0463/16-S	ALLERGAN PHARMACEUTICAL INTERNATIONAL LIMITED	SK
Belkyra 10 mg/ml	SE/H/1547/001	33622	ALLERGAN PHARMACEUTICAL	FI

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injektioneste, liuos			INTERNATIONAL LIMITED	
Belkyra 10 mg/ml injektionsvätska, lösning	SE/H/1547/001	33622	ALLERGAN PHARMACEUTICAL INTERNATIONAL LIMITED	FI
Belkyra 10 mg/ml, roztwór do wstrzykiwań	SE/H/1547/001	23575	ALLERGAN PHARMACEUTICAL INTERNATIONAL LIMITED	PL
BELKYRA 10 mg/ml raztopina za injiciranje	SE/H/1547/001	H/16/02268/001	ALLERGAN PHARMACEUTICAL INTERNATIONAL LIMITED	SI
Belkyra 10 mg/ml soluzione iniettabile	SE/H/1547/001	044896013	ALLERGAN PHARMACEUTICAL INTERNATIONAL LIMITED	IT
Belkyra 10 mg/ml solución inyectable	SE/H/1547/001	81627	ALLERGAN PHARMACEUTICAL INTERNATIONAL LIMITED	ES
Belkyra 10 mg/ml ενέσιμο διάλυμα	SE/H/1547/001	8993/02-02-2017	ALLERGAN PHARMACEUTICAL INTERNATIONAL LIMITED	GR
Belkyra 10 mg/ml solução injetável	SE/H/1547/001	5709563	ALLERGAN PHARMACEUTICAL INTERNATIONAL LIMITED	PT
Belkyra 10 mg/ml Injektionslösung	SE/H/1547/001	2017040065	ALLERGAN PHARMACEUTICAL INTERNATIONAL LIMITED	LU
Belkyra 10 mg/ml solution for injection	SE/H/1547/001	PL 45496/0009	ALLERGAN PHARMACEUTICAL INTERNATIONAL LIMITED	UK
Belkyra 10 mg/ml solution for injection	SE/H/1547/001	PA 2103/003/001	ALLERGAN PHARMACEUTICAL INTERNATIONAL LIMITED	IE
Belkyra, injektionsvæske, opløsning	SE/H/1547/001	59040	ALLERGAN PHARMACEUTICAL INTERNATIONAL LIMITED	DK
Belkyra 10 mg/ml solution injectable	SE/H/1547/001	BE511511	ALLERGAN PHARMACEUTICAL INTERNATIONAL LIMITED	BE
Belkyra 10 mg/ml oplossing voor injectie	SE/H/1547/001	BE511511	ALLERGAN PHARMACEUTICAL INTERNATIONAL LIMITED	BE
Belkyra 10 mg/ml	SE/H/1547/001	BE511511	ALLERGAN PHARMACEUTICAL	BE

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Injektionslösung			INTERNATIONAL LIMITED	
Belkyra 10 mg/ml otopina za injekciju	SE/H/1547/001	HR-H-830108151	ALLERGAN PHARMACEUTICAL INTERNATIONAL LIMITED	HR
Belkyra 10 mg/ml, oplossing voor injectie	SE/H/1547/001	RVG120593	ALLERGAN PHARMACEUTICAL INTERNATIONAL LIMITED	NL
Belkyra 10 mg/ml ενέσιμο διάλυμα	SE/H/1547/001	022447	ALLERGAN PHARMACEUTICAL INTERNATIONAL LIMITED	CY