



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/849048/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance(s): sodium iodide (^{131}i)

Procedure No.: PSUSA/00002753/201703



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
131I-Nátrium-jodid Izotóp Intézet 20 MBq/ml belsőleges oldat	not available	OGYI-T-9680/01	INSTITUTE OF ISOTOPES CO.,LTD.	HU
MONIYOT-131 14,8-3700 MBq/ml	DK/H/1700/001	7748/31-1-2012	MONROL EUROPE SRL	GR
MONIYOT-131 14,8-3700 MBq/ml soluție orală pentru terapie	DK/H/1700/001-003-DC	8895/2016/01-02	MONROL EUROPE SRL	RO
MONIYOT-131 14.8-3700 MBq/ml oral solution for therapeutic use	DK/H/1700/001-003/DC	II-15453	MONROL EUROPE SRL	BG
Moniyot-131 Oral Solution	DK/H/1700/001	02245	MONROL EUROPE SRL	DK
MONIYOT-131 zur Therapie 14,8-3700 MBq/ml Lösung zum Einnehmen	DK/H/1700/001	77453.00.00	MONROL EUROPE SRL	DE
Sodium Iodide (131I) Diagnostic Capsules, GE Healthcare	not available	8349	GE HEALTHCARE LIMITED	NO
THERACAP131 TM	not available	8354	GE HEALTHCARE LIMITED	NO
Natriumjodid (131I) Diagnostikkapseln tvrdá tobolka	not available	88/378/93-C	GE HEALTHCARE LIMITED	CZ
Sodium Iodide (131I) Diagnostic Capsules, GE Healthcare	not available	DK R 1144	GE HEALTHCARE LIMITED	DK
Ioduro (131I) de sodio GE Healthcare 3,7 MBq cápsulas duras	not available	77841	GE HEALTHCARE BIO-SCIENCES, S.A.U.	ES
Sodium (131I) Iodide Injection, GE Healthcare	not available	8351	GE HEALTHCARE LIMITED	NO
Sodium (131I) Iodide Injection, GE Healthcare	not available	8350	GE HEALTHCARE LIMITED	NO
Sodium Iodide (131I) Diagnostic Capsules 0.333-3.7 MBq capsules, hard	not available	PL 00221/0112	GE HEALTHCARE LIMITED	UK
Theracap 37 MBq – 5550 MBq gélules	not available	2012050072	GE HEALTHCARE BVBA	LU
Theracap 37 MBq – 5550 MBq gélules	not available	2012050072	GE HEALTHCARE BVBA	LU
Sodium Iodide [131I] Injection	not available	RVG 57781	GE HEALTHCARE B.V.	NL
Sodium Iodide (131I) Diagnostic Capsules	not available	48636/01/27-2-2002	GE HEALTHCARE LIMITED	GR
Ioduro (131I) de sodio GE Healthcare 74 MBq/ml solución inyectable	not available	78011	GE HEALTHCARE BIO-SCIENCES, S.A.U.	ES
Ioduro (131I) de sodio GE Healthcare 925 MBq/ml solución inyectable	not available	78012	GE HEALTHCARE BIO-SCIENCES, S.A.U.	ES
THERACAP131 37 MBq-5.55 GBq	not available	PL 00221/0102	GE HEALTHCARE LIMITED	UK

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capsules, hard				
Theracap131 37-5550 MBq Hartkapsel	not available	28638.00.00	GE HEALTHCARE BUCHLER GMBH & CO. KG	DE
Theracap131 TM, capsule	not available	1135	GE HEALTHCARE LIMITED	DK
THERACAP131TM kõvakapsel	not available	381202	GE HEALTHCARE LIMITED	EE
THERACAP 37-5.550 MBq cápsulas	not available	74145	GE HEALTHCARE BIO-SCIENCES, S.A.U.	ES
Theracap [131I] 37 MBq - 5,55 GBq kapseli, kova	not available	11204	GE HEALTHCARE LIMITED	FI
Theracap [131I] kemény kapszula terápiás célra	not available	OGYI-T-9732/01	GE HEALTHCARE LIMITED	HU
THERACAP131	not available	88/376/93-C	GE HEALTHCARE LIMITED	CZ
THERACAP131 37-5550 MBq kietosios kapsulės	not available	LT/1/01/2597/001	GE HEALTHCARE LIMITED	LT
Theracap 131, capsules 37-5550 MBq/st	not available	RVG 57765	GE HEALTHCARE B.V.	NL
THERACAP131, kapsułka, 37 - 2035 MBq, 2,22 – 5,55 GBq	not available	8905	GE HEALTHCARE LIMITED	PL
THERACAP 131TM	not available	88/0190/04-S	GE HEALTHCARE LIMITED	SK
Sodium (131I) Iodide Injection, GE Healthcare	not available	DK R 1145	GE HEALTHCARE LIMITED	DK
ТЕРАКАП131 37MBq - 5,55 GBq твърди капсули	not available	II-15119	GE HEALTHCARE BUCHLER GMBH & CO. KG	BG
THERACAP 131	not available	4-00013	GE HEALTHCARE BUCHLER GMBH & CO. KG	AT
Theracap 37 MBq– 5550 MBq Hartkapseln	not available	BE334266	GE HEALTHCARE BVBA	BE
Theracap 37 MBq – 5550 MBq gélules	not available	BE334266	GE HEALTHCARE BVBA	BE
Sodium Iodide (131I) Injection Injekční roztok	not available	88/375/93-C	GE HEALTHCARE LIMITED	CZ
THERACAP131TM	not available	MA 149/00701	GE HEALTHCARE LIMITED	MT
Natriumjodid (131J) Diagnostikkapseln 0,333 - 3,7 MBq Hartkapsel	not available	28637.00.00	GE HEALTHCARE BUCHLER GMBH & CO. KG	DE
THERACAP , 37 – 5550 MBq/ cápsula	not available	4068888	GE HEALTHCARE LIMITED	PT
Sodium Iodide (131I) Diagnostic Capsules	not available	88/0311/08-S	GE HEALTHCARE LIMITED	SK

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THERACAP 37-5550 MBq capsula rigida	not available	039029018	GE HEALTHCARE S.R.L.	IT
Натриев йодид [131 I] инжекция 74 MBq/ml инжекционен разтвор	not available	20060655	GE HEALTHCARE BUCHLER GMBH & CO. KG	BG
Натриев йодид [131 I] инжекция 925 MBq/ml инжекционен разтвор	not available	20060655	GE HEALTHCARE BUCHLER GMBH & CO. KG	BG
Iodură de sodiu (131I) Capsule pentru Diagnostic	not available	5723/2013/01	GE HEALTHCARE LIMITED	RO
Sodium Iodide [131I] Diagnostic Capsules	not available	RVG 57768	GE HEALTHCARE B.V.	NL
Sodium Iodide [131I] Diagnostic Capsules	not available	MA149/00601	GE HEALTHCARE LIMITED	MT
Iodeto de Sódio [131I], Solução Injectável GE Healthcare	not available	4736583	GE HEALTHCARE LIMITED	PT
Iodeto de Sódio [131I], Solução Injectável GE Healthcare	not available	4736484	GE HEALTHCARE LIMITED	PT
IODETO DE SÓDIO [131I], CÁPSULA PARA DIAGNÓSTICO GE HEALTHCARE	not available	4736385	GE HEALTHCARE LIMITED	PT
Sodium Iodide GE Healthcare, [131I] kõvakapslid	not available	413503	GE HEALTHCARE LIMITED	EE
Sodium Iodide [131I] 0,333 - 3,7 MBq kapseli diagnostiikkaan	not available	11203	GE HEALTHCARE LIMITED	FI
Natrii iodidum [131I] šķīdums injekcijām	not available	03-0060	GE HEALTHCARE LIMITED	LV
Natrii iodidum [131I] diagnostiskās kapsulas Nātrija jodīds [131I]	not available	04-0282	GE HEALTHCARE LIMITED	LV
Natrio jodidas [131I] GE Healthcare 0,333 - 3,7 MBq kietosios kapsules	not available	LT/1/04/0001/001	GE HEALTHCARE LIMITED	LT
Sodium Iodide (131I) Injection 74 MBq/ml and 925 MBq/ml solution for injection	not available	PL 00221/0113	GE HEALTHCARE LIMITED	UK
Iodid [131I] NAB 74 oder 925 MBq/ml Injektionslösung, auf Anforderung hergestellt	not available	28799.00.00	GE HEALTHCARE BUCHLER GMBH & CO. KG	DE
Natriumjodid (131J) 37-1110 MBq/ml	not available	6524246.00.01	GE HEALTHCARE BUCHLER	DE

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Injektionslösung, auf Anforderung hergestellt			GMBH & CO. KG	
Natriumjodid (131I) GE Healthcare 74 MBq/ml injektionsvätska, lösning	not available	80016	GE HEALTHCARE LIMITED	SE
Natriumjodid (131I) GE Healthcare 925 MBq/ml injektionsvätska, lösning	not available	80017	GE HEALTHCARE LIMITED	SE
Sodium Iodide (131I) Injection	not available	88/0189/04-S	GE HEALTHCARE LIMITED	SK
Natriumjodid (I-131) GE Healthcare 0,333-3,7 MBq hårda kapslar	not available	80090	GE HEALTHCARE LIMITED	SE
THERACAP131 37 MBq - 5550 MBq capsule tari	not available	9322/2016/01	GE HEALTHCARE LIMITED	RO
Natrio jodidas [131I] GE Healthcare 74 MBq/ml injekcinis tirpalas	not available	LT/1/04/0001/007	GE HEALTHCARE LIMITED	LT
Natrio jodidas [131I] GE Healthcare 74 MBq/ml injekcinis tirpalas	not available	LT/1/04/0001/007	GE HEALTHCARE LIMITED	LT
Natrio jodidas [131I] GE Healthcare 925 MBq/ml injekcinis tirpalas	not available	LT/1/04/0001/008	GE HEALTHCARE LIMITED	LT
Natrio jodidas [131I] GE Healthcare 74 MBq/ml injekcinis tirpalas	not available	LT/1/04/0001/003	GE HEALTHCARE LIMITED	LT
Natrio jodidas [131I] GE Healthcare 74 MBq/ml injekcinis tirpalas	not available	LT/1/04/0001/004	GE HEALTHCARE LIMITED	LT
Natrio jodidas [131I] GE Healthcare 74 MBq/ml injekcinis tirpalas	not available	LT/1/04/0001/005	GE HEALTHCARE LIMITED	LT
Natrio jodidas [131I] GE Healthcare 74 MBq/ml injekcinis tirpalas	not available	LT/1/04/0001/006	GE HEALTHCARE LIMITED	LT
Natrio jodidas [131I] GE Healthcare 925 MBq/ml injekcinis tirpalas	not available	LT/1/04/0001/009	GE HEALTHCARE LIMITED	LT
Natrio jodidas [131I] GE Healthcare 925 MBq/ml injekcinis tirpalas	not available	LT/1/04/0001/010	GE HEALTHCARE LIMITED	LT
Natrio jodidas [131I] GE Healthcare 925 MBq/ml injekcinis tirpalas	not available	LT/1/04/0001/011	GE HEALTHCARE LIMITED	LT
Natrio jodidas [131I] GE Healthcare 925 MBq/ml injekcinis tirpalas	not available	LT/1/04/0001/012	GE HEALTHCARE LIMITED	LT
Natrio jodidas [131I] GE Healthcare 925 MBq/ml injekcinis tirpalas	not available	LT/1/04/0001/013	GE HEALTHCARE LIMITED	LT

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Natrio jodidas [131I] GE Healthcare 925 MBq/ml injekcinis tirpalas	not available	LT/1/04/0001/014	GE HEALTHCARE LIMITED	LT
Natrio jodidas [131I] GE Healthcare 925 MBq/ml injekcinis tirpalas	not available	LT/1/04/0001/015	GE HEALTHCARE LIMITED	LT
Natrio jodidas [131I] GE Healthcare 925 MBq/ml injekcinis tirpalas	not available	LT/1/04/0001/016	GE HEALTHCARE LIMITED	LT
Theracap 37-5550 MBq hård kapsel	not available	80091	GE HEALTHCARE LIMITED	SE