



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 January 2025
EMA/441417/2024
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): iodine (131i) iobenguane

Procedure No. PSUSA/00001764/202405



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]Μετα-ιωδοβενζυλογουανιδίνη για Θεραπευτικούς Σκοπούς 185-740 MBq/ml, διάλυμα προς έγχυση ή ενέσιμο διάλυμα	not available	59083/17-07-2017	GE HEALTHCARE AE	GR
[131I]-Μετα-ιωδοβενζυλογουανιδίνη για Διαγνωστικούς Σκοπούς 9,25-18,5 MBq/ml, ενέσιμο διάλυμα	not available	59083/17-07-2017	GE HEALTHCARE AE	GR
[131I] Мета-йодбензилгуанидин за диагностика 9,25-18,5 MBq/ml инжекционен разтвор	not available	20060672	GE HEALTHCARE BUCHLER GMBH & CO. KG	BG
[131I] Meta-Iodobenzylguanidine for Therapeutic Use, GE Healthcare	not available	DK R 1157	GE HEALTHCARE BUCHLER GMBH & CO. KG	DK
(131I) Meta-Iodobenzylguanidine for Diagnostic Use,GE Healthcare, solution for intravenous injection	not available	DK R 1156	GE HEALTHCARE BUCHLER GMBH & CO. KG	DK
(131I) Meta-Iodobenzylguanidine for Diagnostic Use	not available	MA1299/00301	GE HEALTHCARE BUCHLER GMBH & CO. KG	MT
Meta-Iodobenzilguanidina- ^[131I] para Terapêutica, Solução Injetável, GE Healthcare	not available	4327284	GE HEALTHCARE BUCHLER GMBH & CO. KG	PT
Meta-Iodobenzilguanidina- ^[131I] para Diagnóstico, Solução Injetável GE Healthcare	not available	4327185	GE HEALTHCARE BUCHLER GMBH & CO. KG	PT
MIBG (I-131) GE Healthcare 185 -740 MBq/ml injektions-/infusionsvätska, lösning.	not available	12753	GE HEALTHCARE BUCHLER GMBH & CO. KG	SE
MIBG (I-131) GE Healthcare	not available	12752	GE HEALTHCARE BUCHLER	SE

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
9,25 – 18,50 MBq/ml injektions-/infusionsvätska, lösning.			GMBH & CO. KG	
Meta-Iodobenzylguanidine (131I) for Diagnostic Use 9.25-18.5 MBq/ml solution for injection	not available	PL 00221/0124	GE HEALTHCARE LIMITED	XI
Meta-Iodobenzylguanidine (131I) for Therapeutic Use 185-740 MBq/ml solution for infusion or solution for injection	not available	PL 00221/0125	GE HEALTHCARE LIMITED	XI
131I-MIBG 20 MBq/ml diagnosztikus injekció	not available	OGYI-T-9205/01	INSTITUTE OF ISOTOPES CO.,LTD.	HU
131I-MIBG 370 MBq/ml oldatos injekció	not available	OGYI-T-9197/01	INSTITUTE OF ISOTOPES CO.,LTD.	HU