



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 January 2016
EMA/473854/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: iodine (131i) iobenguane

Procedure no.: PSUSA/00001764/201505



Product Name (in authorisation country)	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
(131i) Meta-Iodobenzylguanidine Diagnostic Dose Ge Healthcare	77773/5-11-2012	Ge Healthcare Ae	Greece
(131i) Meta-Iodobenzylguanidine For Diagnostic Use Ge Healthcare	MA149/00101	Ge Healthcare Limited	Malta
(131i) Meta-Iodobenzylguanidine Ge Healthcare	DK R 1156	Ge Healthcare Limited	Denmark
(131i) Meta-Iodobenzylguanidine Therapeutic Dose Ge Healthcare	77772/5-11-2012	Ge Healthcare Ae	Greece
Iobenguano (131i) D Ge Healthcare	038975013	Ge Healthcare S.R.L.	Italy
M-Iodobenzylguanidin (131i) Zur Therapie Ge Healthcare Limited	88/699/93-C	Ge Healthcare Limited	Czech Republic
Meta-Iodobencilguanidina (131i) Para Uso Diagnóstico Ge Healthcare Bio-Sciences	69.364	Ge Healthcare Bio-Sciences, S.A.U.	Spain
Meta-Iodobenzilguanidina [131 I] Para Diagnóstico Ge Healthcare	4327185	Ge Healthcare Limited	Portugal
Meta-Iodobenzilguanidina [131i] Para Terapêutica Ge Healthcare	4327284	Ge Healthcare Limited	Portugal
Meta-Iodobenzylguanidine (131i) For Diagnostic Use Ge Healthcare	PL 00221/0124	Ge Healthcare Limited	United Kingdom
Meta-Iodobenzylguanidine (131i) For Therapeutic Use Ge Healthcare Limited	PL 00221/0125	Ge Healthcare Limited	United Kingdom

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Meta-Iodobenzylguanidine [131i] Diagnostiseen Käyttöön Ge Healthcare Ltd	11205	Ge Healthcare Limited	Finland
Meta-Iodobenzylguanidine [131i] Terapeuttiseen Käyttöön Ge Healthcare Ltd	11206	Ge Healthcare Limited	Finland
Metaiodobencilguanidina (131i) Para Uso Terapéutico Ge Healthcare	69.329	Ge Healthcare Bio-Sciences, S.A.U.	Spain
Mibg (I-131) Ge Healthcare	12752	Ge Healthcare Limited	Sweden
Mibg (I-131) Ge Healthcare	12753	Ge Healthcare Limited	Sweden
Mibg I-131 Ge Healthcare	18966.00.00	Ge Healthcare Buchler Gmbh & Co. Kg	Germany
Mibg-131 Zur Diagnose Ge Healthcare	18965.00.00	Ge Healthcare Buchler Gmbh & Co. Kg	Germany
[131i] Meta-Iodobenzylguanidine For Diagnostic Use Ge Healthcare	RVG 57706	Ge Healthcare B.V.	Netherlands
[131i] Meta-Iodobenzylguanidine For Therapeutic Use Ge Healthcare	DK R 1157	Ge Healthcare Limited	Denmark
[131i] Meta-Iodobenzylguanidine For Therapeutic Use Ge Healthcare	RVG 57708	Ge Healthcare B.V.	Netherlands

Product Name (in authorisation country)	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
[131i] мета-йодбензилгуанидин за диагностика Ge Healthcare Buchler	II-15025/27.11.2006	Ge Healthcare Buchler Gmbh & Co. Kg	Bulgaria
131I-MIBG 20 MBq/ml solution for injection	OGYI-T-09205/01-03	Izotóp Intézet Kft.	Hungary
131I-MIBG 370 MBq/ml solution for injection	OGYI-T-09197	Izotóp Intézet Kft.	Hungary