

<sup>131</sup> I	<b><sup>131</sup>I-MIBG 20 MBq/ml injection for diagnostic use</b>
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<i>Product code:</i>	<b>I-RAO-1</b>
<i>ATC code:</i>	V09IX02
<i>Marketing Authorisation Number:</i>	<b>20 MBq, OGYI-T-9205/01 40 MBq, OGYI-T-9205/02 80 MBq, OGYI-T-9205/03</b>
<i>Pharmaceutical form and description:</i>	Radioactive sterile injection solution. The active ingredient of the radioactive solution for injection for intravenous use is <sup>131</sup> I radioisotope labelled meta-iodobenzyl-guanidine (MIBG).
<i>Activity per vial:</i>	20 MBq, 40 MBq, or 80 MBq
<i>Specific activity:</i>	≥ 26.7 GBq/g MIBG
<i>Radioactive concentration:</i>	20 MBq/ml
<i>Radionuclidic impurities:</i>	≤ 0.1 %
<i>Radiochemical purity:</i>	> 95 %
<i>pH:</i>	5 – 7
<i>Expiry time:</i>	5 days from manufacturing date
<i>Indications and posology:</i>	<b>Indication field: radioisotope diagnostics</b> Localisation and imaging of neuroendocrine tumours, especially: <ul style="list-style-type: none"> <li>• phaeochromocytoma</li> <li>• neuroblastoma</li> </ul> The recommended individual patient dose is 20 – 40 MBq <sup>131</sup> I-MIBG. To prevent the uptake of the free radioiodine evolving in vivo, thyroid blockade is recommended before the examination. The injection should be administered slowly; time of administration is 2-4 minutes. Rapid administration of MIBG can result in blood pressure increase, allergic symptoms, flush or asthmatic spasms.
<i>Storage:</i>	Store in refrigerator at 2–8 °C. Comply with the regulations for radiation safety.
<i>Packaging:</i>	In type I injection vial (6R) closed with brombutyl stopper and green aluminium cap in lead container with paper insert. (Type A packaging) Pack size: 20 MBq, 40 MBq or 80 MBq (at the indicated calibration date) / vial

### <sup>131</sup>I ISOTOPE DECAY FACTORS

day	hours	0.0	1.0	2.0	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0	12.0
0	0	1.0000	0.9964	0.9928	0.9893	0.9857	0.9822	0.9787	0.9752	0.9717	0.9682	0.9647	0.9613	0.9578
	12	0.9578	0.9544	0.9510	0.9475	0.9441	0.9408	0.9374	0.9340	0.9307	0.9273	0.9240	0.9207	0.9174
1	24	0.9174	0.9141	0.9108	0.9076	0.9043	0.9011	0.8978	0.8946	0.8914	0.8882	0.8850	0.8819	0.8787
	36	0.8787	0.8755	0.8724	0.8693	0.8662	0.8631	0.8600	0.8569	0.8538	0.8507	0.8477	0.8447	0.8416
2	48	0.8416	0.8386	0.8356	0.8326	0.8296	0.8266	0.8237	0.8207	0.8178	0.8148	0.8119	0.8090	0.8061
	60	0.8061	0.8032	0.8003	0.7975	0.7946	0.7918	0.7889	0.7861	0.7833	0.7805	0.7777	0.7749	0.7721
3	72	0.7721	0.7693	0.7666	0.7638	0.7611	0.7584	0.7556	0.7529	0.7502	0.7475	0.7449	0.7422	0.7395
	84	0.7395	0.7369	0.7342	0.7316	0.7290	0.7264	0.7238	0.7212	0.7186	0.7160	0.7134	0.7109	0.7083
4	96	0.7083	0.7058	0.7033	0.7007	0.6982	0.6957	0.6932	0.6907	0.6883	0.6858	0.6833	0.6809	0.6784
	108	0.6784	0.6760	0.6736	0.6712	0.6688	0.6664	0.6640	0.6616	0.6592	0.6569	0.6545	0.6522	0.6498
5	120	0.6498	0.6475	0.6452	0.6429	0.6405	0.6383	0.6360	0.6337	0.6314	0.6291	0.6269	0.6246	0.6224
	132	0.6224	0.6202	0.6179	0.6157	0.6135	0.6113	0.6091	0.6069	0.6048	0.6026	0.6004	0.5983	0.5961
6	144	0.5961	0.5940	0.5919	0.5898	0.5876	0.5855	0.5834	0.5813	0.5793	0.5772	0.5751	0.5730	0.5710
	156	0.5710	0.5689	0.5669	0.5649	0.5628	0.5608	0.5588	0.5568	0.5548	0.5528	0.5508	0.5489	0.5469
7	168	0.5469	0.5449	0.5430	0.5410	0.5391	0.5372	0.5352	0.5333	0.5314	0.5295	0.5276	0.5257	0.5238
	180	0.5238	0.5219	0.5201	0.5182	0.5164	0.5145	0.5127	0.5108	0.5090	0.5072	0.5053	0.5035	0.5017