



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 September 2020
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: iopamidol

Procedure no.: PSUSA/00001771/201912

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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
IOPAMIRO Διάλυμα για στοματική ή ορθική χρήση 61.24% (30% IODINE)	not available	36365/10/18-3-2011	BRACCO IMAGING S.P.A.	GR
Gastromiro 300 mg/ml peroralna ali rektalna raztopina	not available	H/99/00675/001	BRACCO IMAGING S.P.A.	SI
Gastromiro 300 mg/ml peroralna ali rektalna raztopina	not available	H/99/00675/002	BRACCO IMAGING S.P.A.	SI
Gastromiro 300 mg/ml peroralna ali rektalna raztopina	not available	H/99/00675/003	BRACCO IMAGING S.P.A.	SI
Iopamiro 370 mg/ml solución inyectable	not available	57272	BRACCO IMAGING S.P.A.	ES
Iopamiro 300 mg/ml solución inyectable	not available	57273	BRACCO IMAGING S.P.A.	ES
IOPAMIRO Διάλυμα για στοματική ή ορθική χρήση 61.24% (30% IODINE)	not available	36365/10/18-3-2011	BRACCO IMAGING S.P.A.	GR
Gastromiro - nichtionisches Röntgenkontrastmittel - enterale Lösung	not available	1-18981	BRACCO ÖSTERREICH GMBH	AT
Niopam 150, Solution for Injection, glass bottles	not available	PA1826/004/001	BRACCO IMAGING S.P.A.	IE

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
Niopam 200, Solution for Injection, glass bottles	not available	PA1826/004/002	BRACCO IMAGING S.P.A.	IE
Niopam 300, Solution for injection, glass bottles	not available	PA1826/004/003	BRACCO IMAGING S.P.A.	IE
Niopam 340, Solution for Injection, glass bottles	not available	PA1826/004/004	BRACCO IMAGING S.P.A.	IE
Niopam 370, Solution for Injection, glass bottles	not available	PA1826/004/005	BRACCO IMAGING S.P.A.	IE
Gastromiro, drank/klyasma 612,4 mg/ml (300 mg I/ml)	not available	RVG 19306	BRACCO IMAGING S.P.A.	NL
Gastromiro	not available	PL 18920/0036	BRACCO UK LTD	UK
Iopamiro 300 mg/ml injekcinis tirpalas	not available	LT/1/02/2825/001	BRACCO IMAGING S.P.A.	LT
Iopamiro 300 mg/ml injekcinis tirpalas	not available	LT/1/02/2825/002	BRACCO IMAGING S.P.A.	LT
Iopamiro 300 mg/ml injekcinis tirpalas	not available	LT/1/02/2825/003	BRACCO IMAGING S.P.A.	LT

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
Iopamiro 300 mg/ml injekcinis tirpalas	not available	LT/1/02/2825/004	BRACCO IMAGING S.P.A.	LT
Iopamiro 370 mg/ml injekcinis tirpalas	not available	LT/1/02/2825/005	BRACCO IMAGING S.P.A.	LT
Iopamiro 370 mg/ml injekcinis tirpalas	not available	LT/1/02/2825/006	BRACCO IMAGING S.P.A.	LT
Iopamiro 370 mg/ml injekcinis tirpalas	not available	LT/1/02/2825/007	BRACCO IMAGING S.P.A.	LT
Iopamiro 370 mg/ml injekcinis tirpalas	not available	LT/1/02/2825/008	BRACCO IMAGING S.P.A.	LT
Iopamiro 300 mg/ml soluție injectabilă	not available	11766/2019/01	BRACCO IMAGING S.P.A.	RO
Iopamiro 300 mg/ml soluție injectabilă	not available	11766/2019/02	BRACCO IMAGING S.P.A.	RO
Iopamiro 300 mg/ml soluție injectabilă	not available	11766/2019/03	BRACCO IMAGING S.P.A.	RO
Iopamiro 370 mg/ml soluție injectabilă	not available	11767/2019/01	BRACCO IMAGING S.P.A.	RO

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
Iopamiro 370 mg/ml soluție injectabilă	not available	11767/2019/02	BRACCO IMAGING S.P.A.	RO
Iopamiro 370 mg/ml soluție injectabilă	not available	11767/2019/03	BRACCO IMAGING S.P.A.	RO
Iopamiro 370 mg/ml soluție injectabilă	not available	11767/2019/04	BRACCO IMAGING S.P.A.	RO
Йопамиро 300 mg/ml инжекционен разтвор	not available	20030552	BRACCO IMAGING S.P.A.	BG
Йопамиро 370 mg/ml инжекционен разтвор	not available	20030553	BRACCO IMAGING S.P.A.	BG
GASTROMIRO 300, 612,4 mg/ml	not available	183497	BRACCO IMAGING S.P.A.	EE
Gastromiro 612,4 mg/ml Solução oral	not available	2353282	BRACCO IMAGING S.P.A.	PT
Gastromiro 612,4 mg/ml Solução oral	not available	2353381	BRACCO IMAGING S.P.A.	PT
Gastromiro 612,4 mg/ml Solução oral	not available	2353480	BRACCO IMAGING S.P.A.	PT

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
IOPAMIRO 200 mg/ml Soluzione iniettabile	not available	024425011	BRACCO IMAGING S.P.A.	IT
IOPAMIRO 300 mg/ml Soluzione iniettabile	not available	024425023	BRACCO IMAGING S.P.A.	IT
IOPAMIRO 300 mg/ml Soluzione iniettabile	not available	024425035	BRACCO IMAGING S.P.A.	IT
IOPAMIRO 300 mg/ml Soluzione iniettabile	not available	024425047	BRACCO IMAGING S.P.A.	IT
IOPAMIRO 370 mg/ml Soluzione iniettabile	not available	024425050	BRACCO IMAGING S.P.A.	IT
IOPAMIRO 370 mg/ml Soluzione iniettabile	not available	024425062	BRACCO IMAGING S.P.A.	IT
IOPAMIRO 370 mg/ml Soluzione iniettabile	not available	024425074	BRACCO IMAGING S.P.A.	IT
IOPAMIRO 300 mg/ml Soluzione iniettabile	not available	024425100	BRACCO IMAGING S.P.A.	IT
IOPAMIRO 370 mg/ml Soluzione iniettabile	not available	024425112	BRACCO IMAGING S.P.A.	IT

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
IOPAMIRO 150 mg/ml Soluzione iniettabile	not available	024425124	BRACCO IMAGING S.P.A.	IT
IOPAMIRO 150 mg/ml Soluzione iniettabile	not available	024425136	BRACCO IMAGING S.P.A.	IT
IOPAMIRO 150 mg/ml Soluzione iniettabile	not available	024425148	BRACCO IMAGING S.P.A.	IT
IOPAMIRO 300 mg/ml Soluzione iniettabile	not available	024425151	BRACCO IMAGING S.P.A.	IT
IOPAMIRO 370 mg/ml Soluzione iniettabile	not available	024425163	BRACCO IMAGING S.P.A.	IT
IOPAMIRO 300 mg/ml Soluzione iniettabile	not available	024425314	BRACCO IMAGING S.P.A.	IT
IOPAMIRO 370 mg/ml Soluzione iniettabile	not available	024425326	BRACCO IMAGING S.P.A.	IT
Iopamiro 300, 612,4 mg/ml süstelähus	not available	165997	BRACCO IMAGING S.P.A.	EE
Iopamiro 370, 755,3 mg/ml süstelähus	not available	166097	BRACCO IMAGING S.P.A.	EE

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
IOPAMIRO 300, otopina za injekcije	not available	HR-H-140733276	BRACCO IMAGING S.P.A.	HR
IOPAMIRO 370 otopina za injekcije	not available	HR-H-213064000	BRACCO IMAGING S.P.A.	HR
SOLUTRAST® 200 M, 200 mg Iod/ml, Injektionslösung Iopamidol	not available	2518.00.00	BRACCO IMAGING DEUTSCHLAND GMBH	DE
SOLUTRAST® 250 M, 250 mg Iod/ml, Injektionslösung Iopamidol	not available	2518.01.00	BRACCO IMAGING DEUTSCHLAND GMBH	DE
Solutrast® 200, 200 mg Iod/ml, Injektionslösung Wirkstoff: Iopamidol	not available	29273.00.00	BRACCO IMAGING DEUTSCHLAND GMBH	DE
Solutrast® 300, 300 mg Iod/ml, Injektionslösung, Infusionslösung Wirkstoff: Iopamidol	not available	29273.01.00	BRACCO IMAGING DEUTSCHLAND GMBH	DE
Solutrast® 370, 370 mg Iod/ml, Injektionslösung, Infusionslösung Wirkstoff: Iopamidol	not available	4378.02.00	BRACCO IMAGING DEUTSCHLAND GMBH	DE
Solutrast® 250, 250 mg Iod/ml, Injektionslösung Wirkstoff: Iopamidol	not available	4378.03.00	BRACCO IMAGING DEUTSCHLAND GMBH	DE

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
Iopamiro 300 mg I/ml oldatos injekció	not available	OGYI-T-5588/01	BRACCO IMAGING S.P.A.	HU
Iopamiro 300 mg I/ml oldatos injekció	not available	OGYI-T-5588/03	BRACCO IMAGING S.P.A.	HU
Iopamiro 300 mg I/ml oldatos injekció	not available	OGYI-T-5588/04	BRACCO IMAGING S.P.A.	HU
Iopamiro 300 mg I/ml oldatos injekció	not available	OGYI-T-5588/05	BRACCO IMAGING S.P.A.	HU
Iopamiro 370 mg I/ml oldatos injekció	not available	OGYI-T-5588/06	BRACCO IMAGING S.P.A.	HU
Iopamiro 370 mg I/ml oldatos injekció	not available	OGYI-T-5588/07	BRACCO IMAGING S.P.A.	HU
Iopamiro 370 mg I/ml oldatos injekció	not available	OGYI-T-5588/08	BRACCO IMAGING S.P.A.	HU
Iopamiro 370 mg I/ml oldatos injekció	not available	OGYI-T 5588/09	BRACCO IMAGING S.P.A.	HU
Jopamiro 200 mg J/ml - Ampullen	not available	17.300	BRACCO ÖSTERREICH GMBH	AT

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
Jopamiro 300 mg J/ml – Ampullen	not available	17.301	BRACCO ÖSTERREICH GMBH	AT
Jopamiro 300 mg J/ml – Stechampullen	not available	17.302	BRACCO ÖSTERREICH GMBH	AT
Jopamiro 370 mg J/ml – Ampullen	not available	17.303	BRACCO ÖSTERREICH GMBH	AT
Jopamiro 370 mg J/ml – Stechampullen	not available	17.304	BRACCO ÖSTERREICH GMBH	AT
Jopamiro 200 mg J/ml – Infusionsflasche	not available	17.608	BRACCO ÖSTERREICH GMBH	AT
GASTROMIRO 61,2% Soluzione	not available	026899017	BRACCO IMAGING S.P.A.	IT
GASTROMIRO 61,2% Soluzione	not available	026899029	BRACCO IMAGING S.P.A.	IT
GASTROMIRO 61,2% Soluzione	not available	026899031	BRACCO IMAGING S.P.A.	IT
Iopamiro 300 mg/ml raztopina za injiciranje	not available	H/94/00789/001	BRACCO IMAGING S.P.A.	SI

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
Iopamiro 300 mg/ml raztopina za injiciranje	not available	H/94/00789/002	BRACCO IMAGING S.P.A.	SI
Iopamiro 300 mg/ml raztopina za injiciranje	not available	H/94/00789/003	BRACCO IMAGING S.P.A.	SI
Iopamiro 370 mg/ml raztopina za injiciranje	not available	H/94/00789/004	BRACCO IMAGING S.P.A.	SI
Iopamiro 370 mg/ml raztopina za injiciranje	not available	H/94/00789/005	BRACCO IMAGING S.P.A.	SI
Iopamiro 370 mg/ml raztopina za injiciranje	not available	H/94/00789/006	BRACCO IMAGING S.P.A.	SI
Iopamiro 370 mg/ml raztopina za injiciranje	not available	H/94/00789/007	BRACCO IMAGING S.P.A.	SI
NIOPAM 150, solution for injection.	not available	PL18920/0031	BRACCO UK LTD	UK
NIOPAM 200, solution for injection.	not available	PL18920/0032	BRACCO UK LTD	UK
NIOPAM 300, solution for injection.	not available	PL18920/0033	BRACCO UK LTD	UK

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
NIOPAM 340, solution for injection.	not available	PL18920/0034	BRACCO UK LTD	UK
NIOPAM 370, solution for injection.	not available	PL18920/0035	BRACCO UK LTD	UK
Iopamiron 200 (200 mg d'iode par mL), solution injectable	not available	NL 12355 - CIS 64682720	BRACCO IMAGING FRANCE	FR
Iopamiron 300 (300 mg d'iode par mL), solution injectable	not available	NL 12356 - CIS 66694372	BRACCO IMAGING FRANCE	FR
Iopamiron 370 (370 mg d'iode par mL), solution injectable	not available	NL 12357 - CIS 67237394	BRACCO IMAGING FRANCE	FR
Gastromiro 612.4 mg/ml, oral or rectal solution	not available	PA1826/005/001	BRACCO IMAGING S.P.A.	IE
IOPAMIRO 150, ενέσιμο διάλυμα	not available	36358/10/18-3-2011	BRACCO IMAGING S.P.A.	GR
IOPAMIRO 200, ενέσιμο διάλυμα	not available	36359/10/18-3-2011	BRACCO IMAGING S.P.A.	GR
IOPAMIRO 300, ενέσιμο διάλυμα	not available	36361/10/18-3-2011	BRACCO IMAGING S.P.A.	GR

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
IOPAMIRO 370, ενέσιμο διάλυμα	not available	36363/10/18-3-2011	BRACCO IMAGING S.P.A.	GR
Iopamiro 200, oplossing voor injectie 408,2 mg/ml (200 mg I/ml)	not available	RVG 09699	BRACCO IMAGING S.P.A.	NL
Iopamiro 300, oplossing voor injectie 612,4 mg/ml (300 mg I/ml)	not available	RVG 09700	BRACCO IMAGING S.P.A.	NL
Iopamiro 370, oplossing voor injectie 755,3 mg/ml (370 mg I/ml)	not available	RVG 09701	BRACCO IMAGING S.P.A.	NL
Iopamiro 250, oplossing voor injectie 510,0 mg/ml (250 mg I/ml)	not available	RVG 10525	BRACCO IMAGING S.P.A.	NL
Iopamiro 300, 612,4 mg/ml, solução injectável	not available	5348479	BRACCO IMAGING S.P.A.	PT
Iopamiro 370, 755,3 mg/ml, solução injectável	not available	5348503	BRACCO IMAGING S.P.A.	PT
Iopamiro 300, 612,4 mg/ml, solução injectável	not available	8701912	BRACCO IMAGING S.P.A.	PT
Iopamiro 300, 612,4 mg/ml, solução injectável	not available	8701920	BRACCO IMAGING S.P.A.	PT

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
Iopamiro 370, 755,3 mg/ml, solução injectável	not available	8701946	BRACCO IMAGING S.P.A.	PT
Iopamiro 370, 755,3 mg/ml, solução injectável	not available	8701953	BRACCO IMAGING S.P.A.	PT
Iopamiro 300, 612,4 mg/ml, solução injectável	not available	8701961	BRACCO IMAGING S.P.A.	PT
Iopamiro 370, 755,3 mg/ml, solução injectável	not available	8701979	BRACCO IMAGING S.P.A.	PT
Iopamiro 370, 755,3 mg/ml, solução injectável	not available	8701987	BRACCO IMAGING S.P.A.	PT