



**IMPORTANT DRUG INFORMATION  
may be found at the following link:**

<https://www.bracco.com/en-us/product/iomeron-iomeprol-injection-importation-discretion-documentation>

July 6, 2022

**Subject: Temporary importation of Iomeron® (iomeprol injection) to address drug shortage issues**

Dear Healthcare Professional,

Due to the current critical shortages of Omnipaque™ (iohexol injection), Visipaque™ (iodixanol injection), and Ultravist® (iopromide injection) in the U.S. market, Bracco Diagnostics Inc. (hereafter “Bracco”) is coordinating with the U.S. Food and Drug Administration (FDA) to increase the availability of iodinated contrast media indicated for intravascular use.

Accordingly, Bracco has initiated temporary importation of Iomeron® (iomeprol injection), an intravascular iodinated contrast medium, into the U.S. market. This product will be used in adult patients by intravenous or intraarterial route of administration only during the shortage. FDA has not approved Iomeron (iomeprol). Iomeron (iomeprol) drug product is manufactured by BIPSO GmbH in Germany and Patheon Italia S.p.A. in Italy. These facilities are also used to manufacture Bracco’s FDA-approved intravascular iodinated contrast medium Isovue® (iopamidol injection).

FDA’s regulatory discretion for the importation and distribution of Iomeron (iomeprol) is limited to Bracco during the critical U.S. shortages of Omnipaque, Visipaque, and Ultravist.

Effective immediately, and during this temporary period, Bracco will offer the following presentations of Iomeron (iomeprol) to the U.S. market:

<b>Product Description</b>	<b>Iodine Concentration (mg iodine/mL)</b>	<b>Package Size</b>	<b>Lot Number</b>	<b>Label Language</b>	<b>NDC Number</b>	<b>UK SmPC</b>
Iomeron (iomeprol injection) 250	250	56 X 100 mL	2C42685	French	0270-7250-10	Iomeron 250 UK SmPC SD
Iomeron (iomeprol injection) 300	300	56 X 100 mL	2C43416 KP1552A	French	0270-7300-10	Iomeron 300 UK SmPC SD
Iomeron (iomeprol injection) 300	300	10 X 200 mL	KP2701F	English	0270-7300-20	Iomeron 300 UK SmPC SD
Iomeron (iomeprol injection) 300	300	6 X 500 mL	KP2804A	Spanish	0270-9300-06	Iomeron 300 UK SmPC MD

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lomeron (iomeprol injection) 350	350	56 X 100 mL	LP1566C	Russian	0270-7350-10	lomeron 350 UK SmPC SD
lomeron (iomeprol injection) 350	350	30 X 150 mL	2C42507	French	0270-7350-15	lomeron 350 UK SmPC SD
lomeron (iomeprol injection) 350	350	10 X 200 mL	LP2705A	English	0270-7350-20	lomeron 350 UK SmPC SD
lomeron (iomeprol injection) 350	350	6 X 500 mL	LP2807A	Spanish	0270-9350-06	lomeron 350 UK SmPC MD
lomeron (iomeprol injection) 350	350	9 X 500 mL	LP2810B	English	0270-9350-09	lomeron 350 UK SmPC MD
lomeron (iomeprol injection) 400	400	56 X 100 mL	MP1577A	Russian	0270-7400-13	lomeron 400 UK SmPC SD
lomeron (iomeprol injection) 400	400	10 X 100 mL	MP2561C	Portuguese	0270-7400-10	lomeron 400 UK SmPC SD
lomeron (iomeprol injection) 400	400	56 X 100 mL	MP2556A	Polish	0270-7400-16	lomeron 400 UK SmPC SD
lomeron (iomeprol injection) 400	400	30 X 200 mL	MP2702C	Slovenian	0270-7400-20	lomeron 400 UK SmPC SD
lomeron (iomeprol injection) 400	400	9 X 500 mL	MP2807C	English	0270-9400-01	lomeron 400 UK SmPC MD
lomeron (iomeprol injection) 400	400	6 X 500 mL	MP2806A	English	0270-9400-06	lomeron 400 UK SmPC MD
lomeron (iomeprol injection) 400	400	9 X 500 mL	MP2807A	Portuguese	0270-9400-03	lomeron 400 UK SmPC MD

The imported lomeron (iomeprol) was originally labelled for use in countries outside the United States. The bottle and box labels will display the text used when marketing lomeron (iomeprol) in those countries. Note that:

- The prescribing information will be provided with each bottle of lomeron (iomeprol), in the form of the appropriate Summary of Product Characteristics (SmPC) document approved for the U.K.,

which is written in English, and is representative of all Iomeron (iomeprol) SmPCs for that presentation.

- Copies of the U.K. SmPCs accompany this letter, along with images of the U.K. bottle and box labels that will be imported.
- The Iomeron (iomeprol) U.K. SmPCs are available on-line at:  
<https://www.bracco.com/en-us/product/iomeron-iomeprol-injection-importation-discretion-documentation>
- For those bottles and box labels not in English, English translations of these labels are available on-line at:  
<https://www.bracco.com/en-us/product/iomeron-iomeprol-injection-importation-discretion-documentation>

**There are differences among the currently marketed nonionic, low-osmolar iodinated contrast media in their physico-chemical properties**, as can be seen in the below table that compares them at the concentration of 300 mg iodine/mL (except for Visipaque, for which the nearest concentration is 320 mg iodine/mL):

<b>Table of Physico-chemical Properties of Iomeron (iomeprol) vs. Comparable U.S. Marketed Products (using a concentration of 300 mg iodine/mL or nearest equivalent)</b>					
<b>Product</b>	<b>Viscosity (CP)</b>		<b>Osmolality (mOsm/kg water)</b>	<b>Density</b>	<b>pH</b>
	<b>20°C</b>	<b>37°C</b>	<b>37°C</b>	<b>37°C</b>	
Iomeron (iomeprol injection) 300	8.1	4.5	521	1.334	6.5 – 7.2
Isovue (iopamidol injection) 300	8.8	4.7	616	1.339	6.5 – 7.5
Omnipaque (iohexol injection) 300	11.8	6.3	672	1.349	6.8 – 7.7
Optiray <sup>®</sup> (ioversol injection) 300	8.2 (25°C)	5.5	651	1.352	6.0 – 7.4
Ultravist (iopromide injection) 300	9.2	4.9	607	1.322	6.5 – 8.0
Visipaque (iodixanol injection) 320	26.6	11.8	290	1.356	6.8 – 7.7

Iomeron (iomeprol) multi-dose container's administration:

The 500 mL presentations of Iomeron (iomeprol) are multi-dose containers. The U.K. SmPC states that the Iomeron (iomeprol) multi-dose bottle stopper should be pierced only once, and that proper withdrawal cannulas for piercing the stopper and drawing up the contrast medium should be used. For those injectors in which the Iomeron (iomeprol) container would be directly inserted (i.e., there would be no use of a transfer set), the injector manufacturer's procedures for insertion should be followed, keeping in mind that the bottle stopper should be pierced only once.

Microbial contamination studies were performed where Iomeron (iomeprol) solutions in multi-dose containers were inoculated with micro-organisms. These studies demonstrated that Iomeron (iomeprol) solutions are bacteriostatic, with microbial growth not observed over the 10-hour period of the studies.

Based upon these studies, when the 500 mL multi-dose container is used to draw up or administer separate doses of Iomeron (ioimeprol), any unused product remaining in the bottle after 10 hours from the stopper being pierced must be discarded.

**Please see Appendix 1 of this letter for tables showing the differences among the FDA-approved intra-arterial and intravenous indications for Omnipaque (iohexol), Visipaque (iodixanol), Ultravist (iopromide) and Isovue (iopamidol) vs. the intra-arterial and intravenous indications for Iomeron (ioimeprol) approved in the U.K.**

Iomeron (ioimeprol) will be available only by prescription in the U.S. **However, the imported lots do not have the statement "Rx only" on their labeling.** Please refer to the Iomeron (ioimeprol) U.K. SmPC for the product's full prescribing information. In addition, please note the following comments and recommendations:

- There are differences between indications for Iomeron (ioimeprol) approved in the U.K. and approved indications for iodinated contrast media (ICM) in the US. Tables comparing indications for selected FDA approved ICM and Iomeron are provided in Appendix 1.
- We recommend that imported Iomeron (ioimeprol) be administered only by intravenous and intra-arterial routes.
- We recommend that imported Iomeron (ioimeprol) be used only in adult patients. Iomeron adult dosing per the U.K. SmPC is provided in Appendix 2.
- Obtain a history of allergy, hypersensitivity, or hypersensitivity reactions to iodinated contrast agents and always have emergency resuscitation equipment and trained personnel available prior to Iomeron (ioimeprol) administration. Monitor all patients for hypersensitivity reactions.
- Use the lowest necessary dose of Iomeron (ioimeprol) in patients with renal impairment or with congestive heart failure.
- Avoid angiocardiology whenever possible in patients with homocystinuria because of the risk of inducing thrombosis and embolism.
- Thyroid storm has occurred after the intravascular use of iodinated contrast agents in patients with hyperthyroidism, or with an autonomously functioning thyroid nodule. Evaluate the risk in such patients before use of any iodinated contrast agent.
- Administer iodinated contrast agents with extreme caution in patients with known or suspected pheochromocytoma. Inject the minimum amount of contrast necessary, assess the blood pressure throughout the procedure, and have measures for treatment of a hypertensive crisis readily available.
- Severe cutaneous adverse reaction severity may increase and time to onset may decrease with repeat administration of contrast agents; prophylactic medications may not prevent or mitigate severe cutaneous adverse reactions. Avoid administering Iomeron to patients with a history of a severe cutaneous adverse reaction to Iomeron.
- Stop metformin at the time of, or prior to, Iomeron administration in patients with an eGFR between 30 and 60 mL/min/1.73 m<sup>2</sup>; in patients with a history of hepatic impairment, alcoholism or heart failure; or in patients who will be administered intra-arterial iodinated contrast. Re-evaluate eGFR 48 hours after the imaging procedure and reinstitute metformin only after renal function is stable.
- Administration of iodinated contrast agents may interfere with thyroid uptake of radioactive iodine (I-131 and I-123) and decrease therapeutic and diagnostic efficacy in patients with carcinoma of the thyroid. The decrease in efficacy lasts for 6 to 8 weeks.

- Renal toxicity has been reported in a few patients with liver dysfunction who were given an oral cholecystographic agent followed by intravascular iodinated contrast agents. Administration of any intravascular iodinated contrast agent should therefore be postponed in patients who have recently received a cholecystographic contrast agent.

**The Iomeron (iomeprol) barcode may not register accurately on U.S. barcode scanning systems.**

Institutions should manually input the product into their systems and confirm that their systems do not provide incorrect information when the product is scanned. Alternative procedures should be followed to assure that the correct drug product is being used and administered to individual patients.

**To place an order for Iomeron (iomeprol),** please contact Bracco Customer Service at 1-877-272-2269 or at [Bracco.otc@diag.bracco.com](mailto:Bracco.otc@diag.bracco.com). Hours of operation: Monday-Friday 8:30 AM – 6:00 PM EDT, excluding holidays.

**To report quality problems, or if you have any questions** about the information contained in this letter or the use of Iomeron (iomeprol), please contact Bracco Professional Services at 1-800-257-5181, option 2, or at [services.professional@diag.bracco.com](mailto:services.professional@diag.bracco.com).

**To report adverse events** associated with the use of this product, please contact Bracco Drug Safety at 1-800-257-5181, option 1, or at [adverse.events@diag.bracco.com](mailto:adverse.events@diag.bracco.com).

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online:** [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- **Regular Mail or Fax:** Download form [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178 (1-800-332-0178)

Sincerely,

*Alberto Spinazzi*

Alberto Spinazzi, MD  
Senior Vice President  
Chief Medical and Regulatory Officer  
Bracco Group

Attachments:

- Iomeron (iomeprol) U.K. SmPCs
- Images of Iomeron (iomeprol) U.K. Bottle and Box Labels

**Appendix 1. Comparisons of approved uses for iodinated contrast media in shortage and those manufactured by Bracco.**

<b>Table of Approved Intra-arterial Uses for Iodinated Contrast Media in Shortage, and for Those Manufactured by Bracco</b>					
<b>POPULATION/ INDICATION</b>	<b>OMNIPAQUE (iohexol) mg iodine/mL</b>	<b>VISIPAQUE (iodixanol) mg iodine/mL</b>	<b>ULTRAVIST (iopromide) mg iodine/mL</b>	<b>ISOVUE (iopamidol) mg iodine/mL</b>	<b>IOMERON* (iomeprol) mg iodine/mL</b>
<b>ADULTS</b>					
Intra-arterial digital subtraction angiography	140	270, 320			250, 300
Aortography	300, 350		370		350, 400
Angiocardiology	350	320	370	370	300, 350, 400
Visceral arteriography	300, 350	320	370	370	300, 350, 400
Cerebral arteriography	300	320	300	300	250, 300
Peripheral arteriography	300, 350	320	300	300	300, 350, 400
*Approved uses for Iomeron (iomeprol) are from the U.K.					

<b>Table of Approved Intravenous Uses for Iodinated Contrast Media in Shortage, and for Those Manufactured by Bracco</b>					
<b>POPULATION/ INDICATION</b>	<b>OMNIPAQUE (iohexol) mg iodine/mL</b>	<b>VISIPAQUE (iodixanol) mg iodine/mL</b>	<b>ULTRAVIST (iopromide) mg iodine/mL</b>	<b>ISOVUE (iopamidol) mg iodine/mL</b>	<b>IOMERON* (iomeprol) mg iodine/mL</b>
<b>ADULTS</b>					
CT head	240, 300, 350	270, 320	300, 370	250, 300	250, 300, 350
CT body	300, 350	270, 320	300, 370	250, 300	250, 300, 350, 400
Intravenous digital subtraction angiography	350				250, 300, 350, 400
Peripheral venography	240, 300	270		200	250, 300, 350
Excretory urography	300, 350	270, 320	300	250, 300, 370	250, 300, 350, 400
*Approved uses for Iomeron (iomeprol) are from the U.K.					

**Appendix 2. Iomeron (iomeprol injection) adult dosing recommendations per the U.K. Summary of Product Characteristics.**

<b>Table of adult dosing recommendations for Iomeron (iomeprol) 250 single dose (* Repeat as necessary)</b>	
Venography	10 – 100 mL* maximum 250 mL  10 – 50 mL upper extremity 50 – 100 mL lower extremity
Cerebral arteriography	5 – 12 mL*
Digital subtraction angiography	
Intra arterial	
visceral	2 – 20 mL per artery* aorta 25-50 mL* both 250 mL maximum
peripheral	5 – 10 mL per artery* maximum 250 mL
Intravenous	30 – 60 mL* maximum 250 mL
Computed tomography	
brain	50 – 150 mL
body	40 – 150 mL maximum 250 mL
Urography intravenous	50 – 150 mL

<b>Table of adult dosing recommendations for Iomeron (iomeprol) 300 single dose (* Repeat as necessary)</b>	
Peripheral arteriography	10 – 90 mL*
Venography	10 – 100 mL* maximum 250 mL  10 – 50 mL upper extremity 50 – 100 mL lower extremity
Angiocardiology and left ventriculography	30 – 80 mL maximum 250 mL
Cerebral arteriography	5 – 12 mL*

Visceral arteriography	5 – 50 mL* or according to type of examination; maximum 250 mL
Digital subtraction angiography	
Intra arterial	
visceral	2 – 20 mL per artery* aorta 25 – 50 mL* both 250 mL maximum
peripheral	5 – 10 mL per artery* maximum 250 mL
Intravenous	30 – 60 mL* maximum 250 mL
Computed tomography	
brain	50 – 150 mL
body	40 – 150 mL maximum 250 mL
Urography intravenous	50 – 150 mL

**Table of adult dosing recommendations for Iomeron (Iomeprol) 300 multidose (\* Repeat as necessary)**

Computed tomography	
brain	50 – 150 mL
body	40 – 150 mL maximum 250 mL

**Table of adult dosing recommendations for Iomeron (Iomeprol) 350 single dose (\* Repeat as necessary)**

Peripheral arteriography	10 – 90 mL*
Venography	10 – 100 mL* maximum 250 mL  10 – 50 mL upper extremity 50 – 100 mL lower extremity
Aortography	50 – 80 mL
Angiocardiology and left ventriculography	30 – 80 mL maximum 250 mL



Coronary arteriography	4 – 10 mL per artery*
Visceral arteriography	5 – 50 mL* or according to type of examination; maximum 250 mL
Intravenous digital subtraction angiography	30 – 60 mL* maximum 250 mL
Computed tomography	
brain	50 – 150 mL
body	40 – 150 mL maximum 250 mL
Urography intravenous	50 – 150 mL

**Table of adult dosing recommendations for Iomeron (Iomeprol) 350 multidose (\* Repeat as necessary)**

Computed tomography	
brain	50 – 150 mL
body	40 – 150 mL maximum 250 mL

**Table of adult dosing recommendations for Iomeron (Iomeprol) 400 single dose (\* Repeat as necessary)**

Peripheral arteriography	10 – 90 mL*
Aortography	50 – 80 mL
Angiocardiography and left ventriculography	30 – 80 mL maximum 250 mL
Coronary arteriography	4 – 10 mL per artery*
Visceral arteriography	5 – 50 mL* or according to type of examination
Intravenous digital subtraction angiography	30 – 60 mL* maximum 250 mL
Computed tomography of the body	40 – 150 mL maximum 250 mL
Urography intravenous	50 – 150 mL

<b>Table of adult dosing recommendations for Iomeron (Iomeprol) 400 multidose (* Repeat as necessary)</b>	
Computed tomography of the body	40 – 150 mL maximum 250 mL