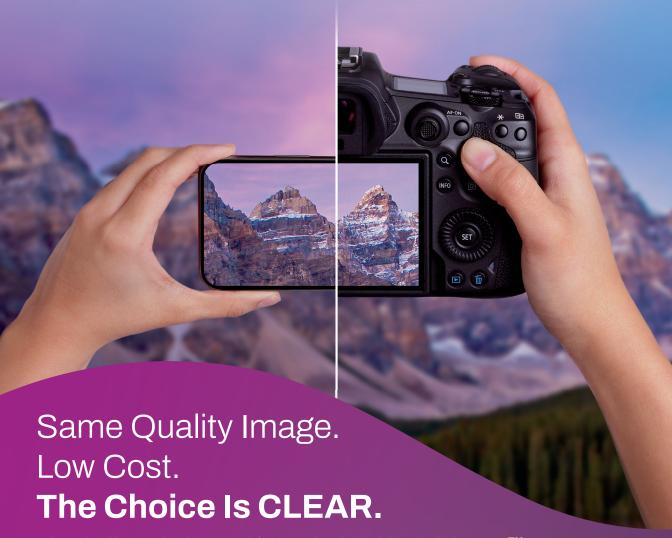
Introducing the **First** and **Only** generic **Iodixanol**.\* By Fresenius Kabi. Same quality images as Visipaque™– at a low cost.

# **Iodixanol**

BY FRESENIUS KABI



Chemically equivalent and fully substitutable to Visipaque™

Angiocardiography:

 lodixanol Injection 320 (iodixanol 320 mg l/mL) is indicated for use in angiocardiography (left ventriculography, aortic root injections and selective coronary arteriography) and can be used in the diagnosis of coronary artery disease as well as evaluation of the function of the chambers of the heart and heart valves.<sup>1</sup>

See page 2 for other indications and safety information.

Comparative clinical significance has not been established.



## Indications and clinical use

#### Angiocardiography:

 Iodixanol Injection 320 (iodixanol 320 mg I/mL) is indicated for use in angiocardiography (left ventriculography, aortic root injections and selective coronary arteriography) and can be used in the diagnosis of coronary artery disease as well as evaluation of the function of the chambers of the heart and heart valves.

#### Arteriography:

- lodixanol Injection 320 is indicated for visualization of the aorta and its branches and for selective peripheral and visceral arteriography and in diagnosing arterial occlusive diseases, aneurysms, arteriovenous malformations and tumors. It may be used for both conventional radiography and digital subtraction angiography (DSA).
- lodixanol Injection 270 (iodixanol 270 mg l/mL) is also indicated for visualization of the aorta and its branches and for selective visceral arteriography and in diagnosing arterial occlusive diseases and tumors.

#### CT scanning of the head:

- lodixanol Injection 320 or Iodixanol Injection 270 administered intravenously is indicated in refining diagnostic precision in areas of the brain that may not otherwise be satisfactorily visualized.
- lodixanol Injection is useful in investigating the presence and extent of malignancies such as gliomas including malignant gliomas, glioblastomas, astrocytomas, oligodendrogliomas and gangliomas, ependymomas, medulloblastomas, meningiomas, neuromas, pinealomas, pituitary adenomas, craniopharyngiomas, geminomas and metastatic lesions. In calcified lesions there is less likelihood of enhancement; following therapy, tumors may show decreased or no enhancement.
- lodixanol Injection may be beneficial in the enhancement of most non-neoplastic lesions, including many cerebral infarcts of recent onset, arteriovenous malformations, and aneurysms.
- Hematomas, intraparenchymal bleeding and clot seldom show enhancement, however, the administration of Iodixanol Injection may still help to rule out any associated arteriovenous malformation. Sites of active infection may be enhanced as well.

#### CT scanning of the body:

 Iodixanol Injection 320 or Iodixanol Injection 270 administered intravenously is indicated for enhancement of computed tomographic images for detection and evaluation of lesions in the liver, pancreas, kidney, aorta, mediastinum, pelvis, abdominal cavity, thoracic space, and retroperitoneal space.

#### **Excretory urography:**

 Iodixanol Injection 320 or Iodixanol Injection 270 administered intravenously is indicated in excretory urography to provide diagnostic contrast of the urinary tract and in the diagnosis of prostate enlargement, renal calculi, obstructive uropathy, urinary tract anomalies, neurogenic bladder, and urinary tract malignancies.

#### Venography:

 Iodixanol Injection 270 administered intravenously is indicated for venography and is useful in the diagnosis of thrombosis, phlebitis, or obstructed venous system.

#### **Contraindications:**

- · Known or suspected hypersensitivity to iodixanol.
- Generally accepted contraindications commonly related to the use of radiopaque contrast media.

#### Most serious warnings and precautions:

#### Injection concentration:

Use the recommended lodixanol Injection concentration for the particular procedure to be undertaken.

#### Other relevant warnings and precautions:

- Hypersensitivity, including serious, life-threatening, fatal anaphylactic/anaphylactoid reactions.
- Known or suspected pheochromocytoma.
- · Sickling in individuals who are homozygous for sickle cell disease.
- Multiple myeloma or other paraproteinemias, particularly those with therapeutically resistant anuria.
- · Benefit/risk ratio assessment in other defined patient groups.
- · Risk of contrast media-induced nephrotoxicity.
- Thromboembolic events due to clotting in vitro when blood remains in contact with syringes, catheters or tubes containing non-ionic contrast media.
- Concurrent medications, including vasopressors, general anesthesia, and metformin.
- · Thyroid dysfunction.
- Patients should be well hydrated prior to and following administration.
- · History of allergy or bronchial asthma.
- · Congestive heart failure.
- Risk of thyroid storm in patients with hyperthyroidism or an autonomously functioning thyroid nodule.
- · Endotoxemia and elevated body temperature.
- · Avoid angiography in patients with homocystinuria.
- Close observation following injection as delayed severe reactions may occur.
- Possibility of dislodging plaques, rupturing aneurysms, or damaging (or perforating) the vessel wall in angiographic procedures.
- Special care in patients with increased intracranial pressure, cerebral thrombosis or embolism, primary or metastatic cerebral lesions, subarachnoid hemorrhage, arterial spasm, transient ischemic attacks, and in any condition when the blood brain barrier is breached or the transit time of the contrast material through the cerebral vasculature is prolonged.
- Severely debilitated patients, particularly those with severe hypertension and impaired renal function.
- Establish presence of a vigorous pulsatile flow when considering aortic injections.
- Avoid entry of a large, concentrated bolus into an aortic branch.
- Extreme caution in considering peripheral angiography in patients suspected of having thromboangiitis obliterans (Buerger's disease).
- Caution in patients with severe ischemia associated with ascending infection. Special care is required in patients with suspected thrombosis, ischemic disease, local infection or a significantly obstructed vascular system.
- When large individual doses are administered, an appropriate time interval should be permitted to elapse between injections to allow for subsidence of hemodynamic disturbances.
- Following catheter procedures gentle pressure hemostasis is advised followed by immobilization of the limb for several hours to prevent hemorrhage from the site of arterial puncture.
- Renal insufficiency.
- Special precautions by indication, including angiocardiography, cerebral arteriography, peripheral and visceral arteriography, venography, excretory urography, and contrast enhanced computed tomography.
- There are no studies on the use of Iodixanol Injection in pregnant women.
- · It is not known to what extent iodixanol is secreted in human milk.
- The safety and effectiveness of Iodixanol Injection for use in children have not been established.
- Generally accepted warnings and precautions commonly related to the use of radiopaque contrast media.
- Laboratory test interactions.

#### For more information:

Please consult the Product Monograph at <a href="https://health-products.canada.ca/dpd-bdpp/">https://health-products.canada.ca/dpd-bdpp/</a> for important information on contraindications, adverse reactions, drug interactions, and dosing/administration that has not been discussed in this piece.

The Product Monograph is also available by calling 1-877-779-7760.

# Dosing

Intraarterial*	Concentration (mg l/mL)	Usual Recommended Single Dose (mL)	Maximum Total Procedural Dosage (mL) 200
Angiocardiography	320		
Left ventricle		20-45	
Left coronary artery		3–10	
Right coronary artery		3–8	
Cerebral Arteriography (A) Conventional	320		175
Carotid artery		10-14	1/5
•			
Vertebral artery		10–12	
(B) Digital Subtraction Angiography (DSA)			175
Carotid artery		5–8	
Vertebral artery		5–8	
Peripheral Arteriography	320		
(A) Conventional			250
Aortography		30-60	
Aortofemoral runoffs		20-90	
Peripheral arteries		15-30	
(B) DSA			250
Aortography / Aortofemoral runoffs		6–15	
Peripheral arteries		3–15	
Visceral Arteriography			
(A) Conventional	320		250
Aortography, including runoffs		30–70	
Major branches of aorta		10-70	
Renal arteries		8–18	
(B) DSA	320	0 10	250
Aortography, including runoffs	020	10–50	200
		2–10	
Major branches of aorta	070	2-10	050
(C) Abdominal DSA	270	00.50	250
Aortography		20–50	
Major branches of aorta		5–30	
Renal arteries		10–25	

Intravenous	Concentration (mg I/mL)	Usual Recommended Single Dose (mL)	Maximum Total Procedural Dosage (mL)
Excretory Urography	270, 320	1/kg (0.27–0.32 g l/kg)	100
Computed Tomography (CT) of the Head	270, 320	100	_
CT of the Body	270, 320	75–150	-
Venography	270	50-150/extremity <sup>†</sup>	_

### Please consult the Product Monograph for complete dosing and administration instructions.

<sup>\*</sup> These doses may be repeated as necessary, up to the procedural maximum dose shown.
† Volume depends on size, flow rate, and disease state of the injected vessel, on the size and condition of the patient, and on the imaging technique used.



# Same Quality Image. Low Cost. **The Choice Is CLEAR.**

## Chemically equivalent and fully substitutable to Visipaque™

lodixanol is available in a range of concentrations and sizes to meet your hospital's needs.1

Product	DIN	Fill size (mL)	FK Order Code	McKesson Order Code	UPC / GTIN Pack of 10
lodixanol 270 mg lodine/mL	02553953	100	CP2779B1	199261	629336006021
		150	CP2780B1	199365	629336006045
lodixanol 320 mg lodine/mL	02553961	50	CP277550	199330	629336006069
		100	CP2776B1	199353	629336006083
		150	CP2777B1	199476	629336006106
		200	CP2778B2	199271	629336006120

Contact your Fresenius Kabi representative for more information.

### Fresenius Kabi: An Experienced, Reliable Supplier

As a leading provider of generic medications, we leverage our 100-year history to deliver innovative therapies that are **safe**, **effective** and **affordable**. Have confidence in our:

- Reliable supply chain.
- Global experience in manufacturing and technology over 90 R&D centres and manufacturing facilities around the world.
- · Outstanding, responsive customer service.



Our Customer Service Department is always happy to help you find the answers you need and provide you with the most up-to-date information For ordering or information, please contact us.

Customer Service hours are:

Monday - Friday, 8:30 a.m. - 4:30 p.m. EST

Toll-Free: 1-877-821-7724 Fax Toll-Free: 1-877-821-2108

Email: canada\_customerservice@fresenius-kabi.com

To learn more about us, please visit our website: www.fresenius-kabi.com/en-ca

Reference: 1. lodixanol Injection 270/lodixanol Injection 320 Product Monograph. Fresenius Kabi Canada Ltd. December 17, 2024.

