

250 mm

include nausea, vomiting, widespread erythema, generalized heat sensation, headache, coryza or laryngeal edema, fever, sweating, asthenia, dizziness, pallor, dyspnea and moderate hypotension. Skin reactions may occur in the form of various types of rash of diffuse blister formation. More severe reactions involving the cardiovascular system such as peripheral vasodilation with pronounced hypotension, tachycardia, dyspnea, agitation, cynosis and loss of consciousness may require emergency treatment.

The use of organic iodine contrast media must be limited to cases for which the diagnostic procedure is definitely indicated as suggested by the patient's clinical status with special attention to existing pathology of the cardiovascular, urinary or hepatobiliary system. In particular, contrast media designed for cardioangiographic procedures should be used in hospitals or clinics equipped and staffed for intensive care in emergencies.or other more common diagnostic procedures wherein iodinated contrast media is used, the public or private institutions where such procedures take place, should be supplied with all the emergency drugs to handle any accident: the Ambo balloon, oxygen bottles, antihistamines, vasopressor drugs, corticosteroids.

Do not mix any other drugs with contrast medium solutions: In patients scheduled for thyroid examination with a radioactive iodine tracer,iodine uptake in the thyroid gland will be reduced for several days (sometimes upto 2 weeks) after dosing with aniodinized contrast medium thatis eliminated through the kidneys.

**Neuroradiology** In the event of CSF blockade, remove as much of the administered contrast solution as possible. The use of organic iodine contrast media may be contraindicated for patients with a history of epilepsy. Also the presence of blood in the CSF contraindicates the use of Iopamiro®: in such cases, the operator should carefully assess the need for the diagnostic procedure against possible risk to the patient. Patients receiving treatment with anticoagulants drugs must continue such treatment before and after the procedure. Should a convulsive seizure develop during the examination, administer diazepam or sodium Phenobarbital intravenously. Neuroleptics must be absolutely avoided because they lower the seizure threshold. The same applies to analgesics, antiemetics, antihistamines and sedatives of the phenothiazine group. Whenever possible, treatment with such drugs should be discontinued at least 48 hours before administration of the contrast medium and not be resumed less than 12 hours after completion of the procedure. Clinical trials have shown that Iopamiro is readily tolerated by the vast majority to patients, both in general terms and, particularly, in terms of CNS tolerability.

**Angiography** In patients undergoing angiocardiographic procedures special attention should be paid to the status of the right heart and pulmonary circulation. Right heart insufficiency and pulmonary hypertension may precipitate bradycardia and systemic hypotension, when the organic iodine solution is injected. In paediatric roentgenology, one should proceed with great caution when injecting the contrast medium into the right heart chambers of cyanotic neonates with pulmonary hypertension and impaired cardiac function. In examinations of the aortic arch the tip of the catheter should be positioned carefully to avoid hypotension, bradycardia and CNS injury due to excess pressure transmitted from the injector pump to the brachiocephalic branches of the aorta. Likewise, in abdominal aortography, excess pressure from the pump may cause renal infarction, spinal cord injury, retroperitoneal bleeding, intestinal infarction and necrosis. In peripheral arteriography Iopamidol 370 may sometimes cause a painful reaction in the involved limb. This is usually not the case with the less concentrated solution Iopamidol 300. A property of nonionic contrast media is the extremely low interference with normal physiological functions. As a consequence of this nonionic contrast media have less anticoagulant activity in vitro than ionic media. Medical personnel performing vascular catheterization procedures should be aware of this and pay meticulous attention to the angiographic technique and catheter flushing so as to minimize the risk of procedure-related thrombosis and embolism.

**Precautions:**

Keep Iopamidol solutions away from strong light. Sometimes crystallization of Iopamidol solutions may occur. The cause of this is a damaged or defective container and therefore the product shouldn't be used in this case. Even invisible damage caused to the container during storage or transit may result in contamination. Before using check visually and don't use if precipitates or particular matter observed or contents not clear and return for replacement. The bottle once opened must be used immediately. Any residue of contrast medium must be discarded. Iopamidol as other iodinated contrast media can react with metallic surfaces containing copper (e.g. brass), therefore the use of equipment in which the product comes into direct contact with such surfaces should be avoided.

**Interactions with Other Medicaments**

**Metformin**

Concurrent use of metformin is contraindicated in patients receiving intravascular iodinated contrast media. Injection of iodinated contrast materials in metformin treated patients has been associated with lactic acidosis and can lead to acute renal failure.

**Pregnancy and Lactation**

Pregnant women and patients with hyperthyroidism should receive iodinated contrast media only if the attending physician finds it absolutely necessary.

**Adverse Effects/Undesirable Effects:**

Skin and Subcutaneous Tissue Disorders

Severe cutaneous adverse reactions [e.g. Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS) and acute generalised exanthematous pustulosis (AGEP)] have been reported in post-marketing experience of iodinated contrast media.

Post-marketing Experience

Endocrine disorders

Frequency 'not known': hypothyroidism

**Side Effects**

The use of Iopamidol as a contrast medium for cerebral angiography may cause side effects which are usually mild and of short duration. Many patients report a sensation of heat in the face and neck; a few complain of headache. A fairly frequent cardiovascular reaction to dosing with Iopamidol is bradycardia associated with systemic hypotension.

The reaction is transient and requires no treatment. Severe neurological sequelae may arise as direct complications of preexisting pathology in the individual patient. Such reactions are diverse and may include tonic/clonic convulsions, aphasia, fainting, and transient narrowing of visual field, hemiparesis and coma. The risk associated with a particular investigation involved may be increased by conditions such as advanced arteriosclerosis, hypertension, heart failure, major systemic diseases and recent cerebral embolism or thrombosis.

In patients undergoing angiographic procedures special attention should be paid to the status of the right heart and pulmonary circulation. Right heart insufficiency and pulmonary hypertension may precipitate bradycardia and systemic hypotension, when the organic iodine solution is injected. In examination of the aortic arch, the tip of the catheter should be positioned carefully to avoid hypotension, bradycardia and CNS injury due to excess pressure transmitted from injector pump to the branchiocephalic branches of the aorta. Likewise in abdominal aortography, excess pressure from the pump may cause renal infarction, spinal cord injury, retroperitoneal bleeding, intestinal infarction and necrosis. In peripheral Iopamidol may sometimes cause a painful reaction in the involved limb. This usually not the case with the less concentrated solution Iopamidol. A property of nonionic contrast media is the extremely low interference with normal physiological functions. As a consequence of this, nonionic contrast media have less anticoagulant activity in-vitro than ionic media. Medical personnel performing vascular catheterization procedures should be aware of this and pay meticulous attention to the angiographic technique and catheter flushing so as to minimize the risk of procedure related thrombosis and embolism.

**Symptoms and Treatment of Overdose**

Overdosage may occur. The adverse effects of overdosage are life-threatening and affect mainly the pulmonary and cardiovascular systems. The symptoms include: cyanosis, bradycardia, acidosis, pulmonary hemorrhage, convulsions, coma, and cardiac arrest. Treatments of an overdosage are directed toward the support of all vital functions, and prompt institution of symptomatic therapy.

**Storage Condition**

Store in a dry place, below 30°C & Protect from light and secondary X-rays

**Shelf Life**

4 Years from the date of manufacture.

**Presentation:**

50ml and 100ml clear glass vial USP type I closure with 32mm bromo butyl closure (plug) and 33 mm aluminium flip off seal.



**Manufactured in India by:**  
**UNIQUE PHARMACEUTICAL LABORATORIES**  
(A div of J.B. Chemicals & Pharmaceuticals Ltd)  
Plot No. 4, Phase-IV, GIDC Industrial Area,  
Panoli - 394 116, Dist-Bharuch  
Revised Package insert: Jan. 2024

Product Registration Holder and Imported by:  
**UNIMED SDN BHD**  
53, Jalan Tembaga SD 5/2B  
Bandar Sri Damansara 52200,  
Kuala Lumpur, Malaysia

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**PAMIDOL INJECTION 370mg  
(Iopamidol Injection USP)**

**Composition for pamidol injection 370mg**

Each ml contains  
Iopamidol USP 755.3 mg equivalent to 370 mg of Iodine  
Excipients: Water for Injection B.P q.s, Tromethamine USP 1mg per ml,  
Edetate Calcium Disodium USP (on anhydrous basis) 0.37mg per ml

**Description:**

Clear, colourless to pale yellow slightly viscous liquid, free from foreign matter.

**Pharmacodynamics**

Iopamidol is contrast medium belonging to the new generation of non-ionic compounds, which are water water-soluble because its molecular structure incorporates Hydrophilic groups. This new class of contrast media differs significantly from other compounds used in other radiological procedures, all of which are soluble only when the radiopaque molecule is ionized by forming a salt with sodium and or meglumine. Such products have been shown to have good tolerability but due to its inherently high osmality this is responsible for a number of side effects that may occur after administration. Non-Ionic contrast agents have resulted in decrease in the general toxicity and improvement both in the local and tissue tolerability as well as by the more delicate structures of the human body such as vascular endothelia and the central nervous system.

Iopamidol has been shown to be effective as an X-ray contrast medium in neuroradiology, angiography, venography, arthrography, urography, cerebral angiography and left ventriculography and coronary arteriography.

**Pharmacokinetics**

The pharmacokinetics of Iopamidol conforms to an open two compartment pharmacokinetic model with first order elimination.

Distribution volume is equivalent to extracellular fluid.

Elimination is almost completely through the kidneys. Less than 1% of the administered dose has been recovered in the faeces up to 72 hours after dosing. Elimination is rapid; up to half the administered dose may be recovered in the urine in the first two hours of dosing.

There is no evidence of biotransformation.

Serum protein binding is negligible.

**Indication**

Angiography: Cerebral arteriography, coronary arteriography, thoracic aortography, abdominal aortography, angiocardiography, selective visceral arteriography, peripheral arteriography, venography, digital subtraction angiography (DSA), DSA of cerebral arteries, DSA of peripheral arteries, DSA of abdominal arte<sup>RES</sup>

**Recommended Dose**

Pamidol 370mg:

| Procedure                                                                                                                                    | Dosage                                                                                                                                          |
|----------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|
| Peripheral Arteriography                                                                                                                     | Adults 20 - 50 ml *<br>Children **                                                                                                              |
| Venography                                                                                                                                   | Adults 20 - 50 ml *<br>Children **                                                                                                              |
| Angiocardiography and Left Ventriculography                                                                                                  | Adults 30 - 80 ml<br>Children **                                                                                                                |
| Coronary Arteriography                                                                                                                       | Adults 4 - 8 ml per artery *                                                                                                                    |
| Aortography - Retrograde                                                                                                                     | Adults 30 - 80 ml<br>Children **                                                                                                                |
| Selective Renal Arteriography                                                                                                                | Adults 5 - 10 ml<br>Children **                                                                                                                 |
| Selective Visceral Angiography:<br>Hepatic<br>Coeliac<br>Superior mesenteric, inferior mesenteric                                            | Adults 30 - 70 ml<br>40 - 70 ml<br>5 - 30 ml<br>Children **                                                                                     |
| Digital Subtraction Angiography:<br>Intravenous injection<br>Left ventriculography<br>Selective coronary arteriography by intra-arterial DSA | Adults 50 ml<br>Children 0.5 - 0.75 ml/kg<br>Adults 25 ml<br>Children 1 - 1.5 ml/kg<br>Adults 2 - 5 ml                                          |
| Intravenous Urography                                                                                                                        | Adults 40 - 80 ml<br>In severe renal failure the usual high dose methods should be employed. (up to 1.5 mg/kg or **)<br>Children 1- 2.5 ml/Kg** |

\*repeat as necessary; \*\* according to body size and age;

Do not exceed 250 ml. Single injection volume depends on the vascular area to be examined

Elderly: dosage as for adults. The lowest effective dose should be used.

**Method of administration**

No other drugs should be mixed with the contrast medium.

*Peripheral arteriography and phlebography (venography)*

Percutaneous injection into the appropriate blood vessel is used for visualisation of peripheral arteries and veins.

*Angiocardiography, left ventriculography, selective coronary arteriography*

Iopamidol may be administered by rapid injection through a catheter into a suitable peripheral artery or vein. It can also be introduced under pressure through a cardiac catheter into any of the heart chambers, or injected into large vessels for immediate visualisation.The contrast medium may also be administered during selective catheterisation of the coronary arteries.

*Aortography*

The contrast medium may be introduced directly by intra-arterial injection (retro-grade method) for visualisation of the aorta and its main branches.

*Selective visceral angiography*

Visualisation can be achieved by selective catheterisation and injection into the hepatic, coeliac or mesenteric arteries.

*Digital subtraction angiography*

For cardiac imaging the contrast medium may be administered intra-arterially by selective catheterisation to provide subtracted images. Iopamidol 370 injected intravenously either centrally or peripherally is also recommended for use in this modality.

*Urography*

The contrast medium is injected intravenously and rapidly eliminated through the kidneys. In patients with severe renal failure, high dose urography should be used.

**Mode of Administration**

Intravascular Injection

**Contraindication**

There are no definite or absolute contraindications to the use of Iopamidol with the possible exception of Waldenstrom's macroglobulinemia, multiple myeloma and severe liver and kidney diseases.

A) Administration of intrathecal Iopamidol with intrathecal corticosteroids B) Immediate repeat myelography C) Intrathecal administration in the presence of significant local or systemic infection where bacterial is likely

**Warnings & Precautions:**

Thyroid Dysfunction

Thyroid dysfunction characterized by hypothyroidism or transient thyroid suppression has been reported in pediatric patients 0-3 years of age after exposed to iodinated contrast media. Younger age, very low birth weight, prematurity and other conditions are associated with an increased risk. If thyroid dysfunction is detected, treat and monitor thyroid function as clinically needed.

**Warnings:**

The use of organic iodine compounds may cause untoward side effects and manifestations of anaphylaxis. The symptoms

31.25 mm

110 mm

Color :



Black