**Scanlux®**

Non-ionic, low-osmolar contrast media for intravenous or intra-arterial use

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**Scanlux® 300 mg/ml**
Solution for injection

**Scanlux® 370 mg/ml**
Solution for injection

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**Therapeutic indications**

- X-ray contrast media for
  - peripheral arteriography (20 - 50 ml)
  - venography (20 - 50 ml)
  - digital subtraction angiography:
    - intra-arterial injection (0.5 - 20 ml)
    - left ventriculography (25 ml)
  - computed tomography enhancement:
    - whole body scanning (40 - 100 ml)
  - intravenous urography (40 - 80 ml)

- X-ray contrast media for
  - peripheral arteriography (20 - 50 ml)
  - angiography & left ventriculography (30 - 80 ml)
  - coronary arteriography (4 - 8 ml per artery)
  - digital subtraction angiography:
    - intravenous injection (30 - 50 ml)
    - left ventriculography (25 ml)
    - selective coronary arteriography by intra-arterial DSA (2 - 5 ml)
  - intravenous urography (40 - 80 ml)

The doses are recommended as a guide. The dosage must be adapted to the examination, the age, body weight, cardiac output, renal function, general condition of the patient and the technique used. Usually the same iodine concentration and volume are used as for other iodinated X-ray contrast media in current use. As with all contrast media, the lowest dose necessary to obtain adequate visualisation should be used.

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**Qualitative and quantitative composition**

- One ml of solution for injection contains 612 mg Iopamidol corresponding to 300 mg iodine
- Osmolality at 37 °C: 635.9 mosmol/kg
- Viscosity at 37 °C: 4.5 mPa s

- One ml of solution for injection contains 755 mg Iopamidol corresponding to 370 mg iodine
- Osmolality at 37 °C: 834.8 mosmol/kg
- Viscosity at 37 °C: 9.0 mPa s

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**Nature and contents of container**

Scanlux® 300 mg/ml and Scanlux® 370 mg/ml are available in 50 ml and 100 ml clear Type II glass bottles with bromobutyl stoppers.

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**Pack sizes**

10 x 50 ml, 10 x 100 ml
Posology and Method of Administration

Please refer to patient leaflet. 

Contra-indications

Iopamidol should be strictly contraindicated in patients with manifest hyperthyroidism. Hypersensitivity to iopamidol or to any of the excipients. 

Special Warnings and Precautions for Use

As with all other contrast media this product may provoke anaphylaxis or other major allergic reactions with angioneurotic oedema, dyspnoea, urticaria and hypotension. A positive history of allergy, asthma or untoward reaction during previous similar investigations indicates a need for extra caution; the benefits may outweigh the risks in such patients. Pre-treatment with antihistamines or corticosteroids to prevent or minimise possible allergic reactions to the contrast media may be considered. Appropriate resuscitative measures should be immediately available.

Patients must be suitably hydrated before and after radiographic procedures. Patients with liver or renal or cardiac disease or pre-existing heart disease, in whom oedema may occur, should be hydrated. Anuria or oliguria may sometimes indicate dehydration. 

As in the case of all iodinated contrast agents, iopamidol can cause severe or fatal intolerance reactions. Blood pressure may fall, and the patient may experience nausea, vomiting, hypothermia, respiratory distress, severe tachycardia, convulsions, unconsciousness, dysrhythmias, shock or death. These reactions which occur when the contrast media are better tolerated, the contrast medium should be warmed up to body temperature before administration.

Cardiovascular disorders: Mainly after cardiovascular procedures/interventions: tachycardia, bradycardia, extrasystoles, transient muscular pains and transient elevations in the serum transaminases. The QT interval on the ECG, increased in these patients. 

CV disorders: Nausea, vomiting, anorexia, severe retching and choking, abdominal pain.

Cardiovascular toxicity usually follows a circadian course. It may occur up to 6 weeks after the injection. 

Nervous system disorders: Seizures, unconsciousness, respiratory depression, cortical blindness.

Exposure to radiocontrast agents is associated with hypothermia, which is reversible. The hypothermia may be severe, and death has occurred in some cases. In hypothermic animals, a large volume of contrast medium is required to produce a significant hypothermia.

Interactions with other Medicinal Products and other forms of Interaction

In contrast to many other contrast media, iopamidol is essentially "sodium-free". In patients with hyponatraemia the administration of iopamidol may result in a rapid increase in serum sodium concentrations. In patients with heart failure the possibility of development of cerebral oedema should not be overlooked.

Psychotropic drugs e.g. antipsychotic and analeptic drugs, tricyclic antidepressants and monoamine oxidase inhibitors should be stopped for 2-6 weeks.

In angiographic procedures, the possibility of dislodging plaque or damaging or perforating the vessel wall should be considered.

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Contraindications to the use of iopamidol should be taken into consideration in patients undergoing angiography. 

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Patients with severe hepatic, renal or combined hepato-renal insufficiency should not be examined unless absolutely indicated. Re-examination should be delayed for 1-3 days.

In angiographic and interventional procedures special attention should be paid to the status of the right heart and pulmonary circulation. Right heart insufficiency may precipitate bradycardia and systemic hypotension, when the organic iodine solution is injected. Right heart angiography should be carried out only when absolutely indicated.

Distances, which may be associated with a transitory increase in the circulating renal blood flow, may be increased for 1-2 hours after the procedure.

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Patients with hepatoencephalopathy may develop severe neurological complications after the administration of iodinated contrast media. Painful dystrophic reactions have been seen on very rare occasions.

Iopamidol injection should be used with caution in patients with hypercalcaemia and cerebral vascular dissection. It is possible that hyperthyroidism may recur in patients previously treated for Graves' disease.

Patients who are known epileptic or have a history of epilepsy should have the condition monitored. In such cases, prophylactic anticonvulsant therapy may be increased for 1-2 hours before the examination.

The administration of vasopressors strongly potentiates the neurological effects of intra-arterial contrast administration.

Arterial thrombosis has been reported when iopamidol was given following papaverine.

Diarrhoea, vomiting, anorexia, severe retching and choking, abdominal pain.

There is an increased risk of severe reactions in patients with severe cardiac disease, particularly in those who have undergone recent coronary artery or cardiac valve surgery. 

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Pre-existing heart disease.

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CV disorders: Nausea, vomiting, anorexia, severe retching and choking, abdominal pain.

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Nervous system disorders: Seizures, unconsciousness, respiratory depression, cortical blindness.

Exposure to radiocontrast agents is associated with hypothermia, which is reversible. The hypothermia may be severe, and death has occurred in some cases. In hypothermic animals, a large volume of contrast medium is required to produce a significant hypothermia.

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