there's more to see...

Scanlux®

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

Scanlux® 300 mg I/ml
Solution for injection

Scanlux® 370 mg I/ml
Solution for injection

Therapeutic indications and recommended posology*

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)
- angiocardiography & 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.

* for adults; for recommended posology for children please refer to SmPC

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

Nature and contents of container

Scanlux® 300 mg I/ml and Scanlux® 370 mg I/ml are available in 50 ml, 100 ml and 200 ml clear Type II glass bottles with bromobutyl stoppers.

Pack sizes

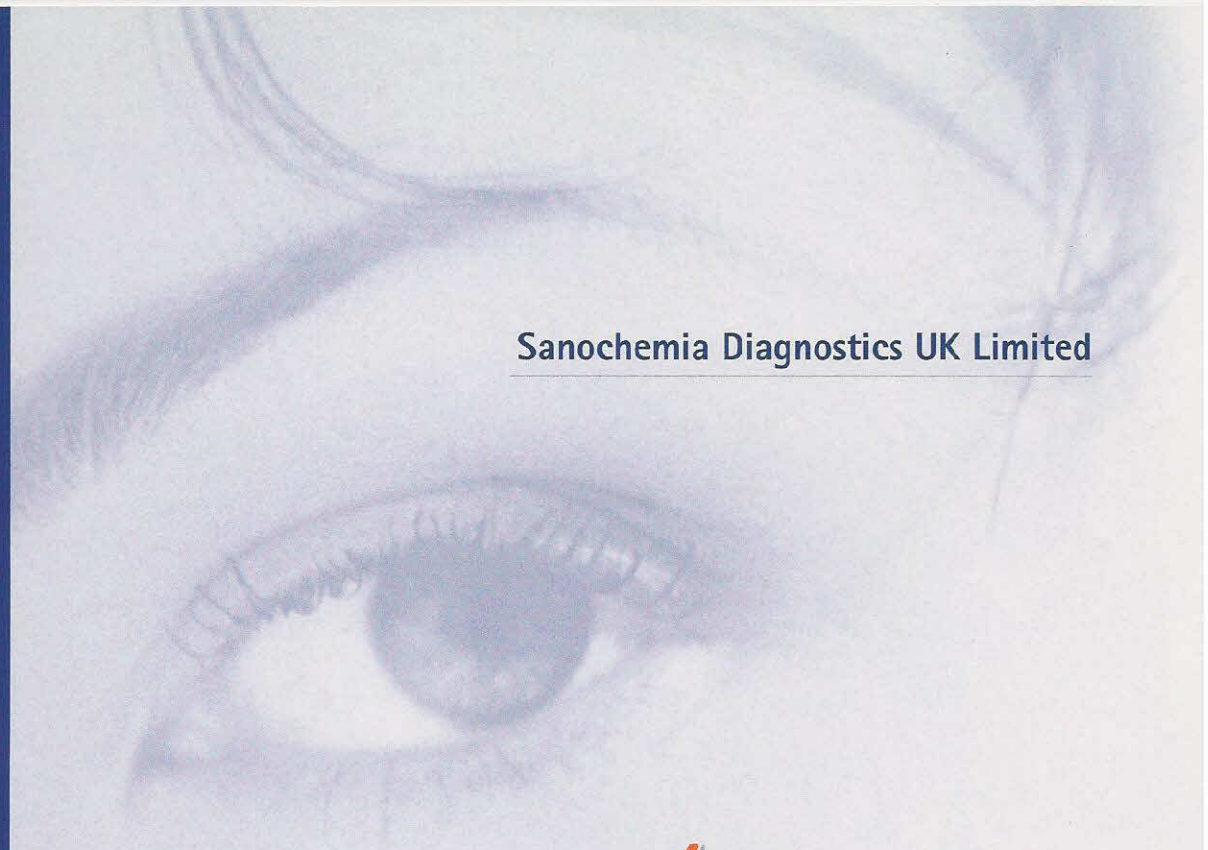
10 x 50 ml, 10 x 100 ml, 10 x 200 ml

600646/00

SANOCHEMIA
Diagnostics International

there's more to see...

Sanochemia Diagnostics UK Limited



NEW

Scanlux®

Scanlux® 300 mg/ml

Scanlux® 340 mg/ml

Scanlux® 370 mg/ml

active substance: iopamidol

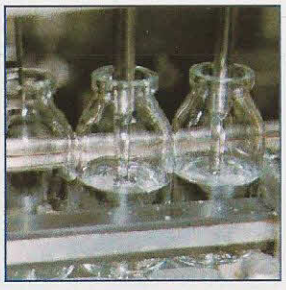
Recognising you have a choice!

SANOCHEMIA
Diagnostics UK Limited

Recommended Dosage Guide

Procedure	Iopamidol Injection Product	Adult Dose	Child Dose
Peripheral Arteriography	Scanlux® 300 mg/ml, 340 mg/ml or 370 mg/ml	20-50 ml*	Children**
Venography	Scanlux® 300 mg/ml	20-50 ml	Children**
Angiocardiography and Left Ventriculography	Scanlux® 340 mg/ml or 370 mg/ml	30-80 ml	Children**
Coronary Angiography	Scanlux® 340 mg/ml or 370 mg/ml	4-8 ml per artery*	
Intraarterial DSA	Scanlux® 300 mg/ml	0.5-20 ml	0.25-0.375 ml/kg**
Intravenous DSA	Scanlux® 340 mg/ml, 370 mg/ml	30-50 ml	0.5-0.75 ml/kg**
Left Ventriculography by DSA	Scanlux® 300 mg/ml, 340 mg/ml or 370 mg/ml	25 ml	0.5-0.75 ml/kg**
Selective coronary arteriography by intraarterial DSA	Scanlux® 340 mg/ml or 370 mg/ml	2-5 ml	
Computed Tomography Enhancement	Scanlux® 340 mg/ml Scanlux® 300 mg/ml	Brain scan 50-100 ml Whole body scanning 40-100 ml	
Intravenous Urography	Scanlux® 300 mg/ml, 340 mg/ml or 370 mg/ml	Adults 40-80 ml. In severe renal failure the usual high dose methods should be employed (up to 1.5 ml/kg).	1-2.5 ml/kg or**

* Repeat as necessary
** According to body size and age



there's more to see...

According to SmPC approved in COO Austria

Pharmacotherapeutic group
Water soluble, nephrotropic, low osmolar X-ray contrast media

ATC code
V08AB04

Contra-indications
Iopamidol is 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 manifestations of allergy with nausea, vomiting, dyspnoea, erythema, urticaria and hypotension. A positive history of allergy, asthma or untoward reaction during previous similar investigations indicates a need for extra caution; the benefit should clearly outweigh the risk in such patients. Pre-treatment with antihistamines or corticosteroids to prevent or minimise possible allergic reactions in such patients may be considered. Appropriate resuscitative measures should be immediately available.
Patients must be sufficiently hydrated before and after radiographic procedures.
Patients with severe functional impairment of the liver or myocardium, myelomatosis, diabetes, polyuria or oliguria, hyperuricemia, infants, elderly patients and patients with severe systemic disease should not be exposed to dehydration.
Abnormalities of fluid or electrolyte balance should be corrected prior to use.
In patients with impairment of renal function, the administration of potentially nephrotoxic drugs should be avoided until the contrast medium is completely excreted. Further administration of contrast media should be postponed until renal function has returned to its previous level.
As experience shows that warmed contrast media are better tolerated, the contrast medium should be warmed up to body temperature before administration.
Patients with severe hepatic, renal or combined hepato-renal insufficiency should not be examined unless absolutely indicated. Re-examination should be delayed for 5–7 days.
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. Right heart angiography should be carried out only when absolutely indicated.
During intracardiac and/or coronary arteriography, ventricular arrhythmias may infrequently occur.
Patients who are known epileptic or have a history of epilepsy should have their medicine maintained. In some instances, anticonvulsant therapy may be increased for 48 hours before the examination.
Use of this product may interfere with tests for thyroid function.
Iopamidol Injection should be used with caution in patients with hyperthyroidism. It is possible that hyperthyroidism may recur in patients previously treated for Graves' disease.
Non-ionic contrast media have less anti-coagulant activity in-vitro than ionic media. Meticulous attention should therefore be paid to angiographic technique. Non-ionic media should not be allowed to remain in contact with blood in the syringe and intravascular catheters should be flushed frequently, to minimise the risk of clotting, which rarely has led to serious thromboembolic complications after procedures.
Patients with phaeochromocytoma can develop severe hypertensive crises following intravascular iopamidol administration. Premedication with α-receptor blockers is recommended.
In patients with monoclonal gammopathy (myelomatosis, Waldenström's macroglobulinaemia), the intravascular administration of contrast media is potentially hazardous. In such patients, the risk of deterioration in renal function can be diminished if the patient is well hydrated before administration.
To prevent crises in patients with sickle cell disease adequate hydration should be assured and a minimal volume of low concentration should be used.
Local tissue irritation can occur in the case of perivascular infiltration of the contrast media.
As in the case of all iodinated contrast agents, iopamidol can cause severe or fatal intolerance reactions. During the examination an intravenous route for emergency treatment in the event of a reaction is required. Drugs and equipment must be available for emergency resuscitation.
Patients with congestive heart failure should be observed for several hours following the procedure to detect delayed haemodynamic disturbances, which may be associated with a transitory increase in the circulating osmotic load. **All other patients should be observed for at least one hour after the procedure, as most of the adverse events occur in this period.** The patient should also be informed that allergic reactions may develop up to several days after the procedure; in such case, a physician should be consulted immediately.
In neonates, and particularly in premature neonates, it is recommended that tests of thyroid function (typically TSH and T4), should be checked 7–10 days and 1 month after the administration of iodinated contrast media because of the risk of hypothyroidism due to iodine overload.
In angiographic procedures, the possibility of dislodging plaque or damaging or perforating the vessel wall should be considered during catheter manipulation and contrast medium injection. Test injections to ensure proper catheter placement are recommended.
Angiography should be avoided whenever possible in patients with homocystinuria due to an increased risk of thrombosis and embolism.
In patients undergoing peripheral angiography, there should be pulsation in the artery into which the X-ray contrast medium will be injected. In patients with thromboangiitis obliterans or ascending infections in combination with serious ischaemia the angiography should be performed, if at all, with special caution.
In patients undergoing venography, special caution should be exercised in patients with suspected phlebitis, serious ischaemia, local infections, or a complete venous occlusion.
The administration of iodinated contrast media may aggravate the symptoms of myasthenia gravis.
Iopamidol injection should be used with caution in patients with hypercalcaemia and cerebral vascular disease.
No other drugs or contrast media should be mixed with iopamidol solution for injection.
This medicinal product contains less than 1 mmol of sodium (23 mg) per maximum 250 ml dose, i.e. essentially "sodium-free".

Interactions with other Medicinal Products and other forms of Interaction
Following administration of iopamidol, the capacity of the thyroid tissue to take up iodine is reduced for 2–6 weeks.
Arterial thrombosis has been reported when iopamidol was given following papaverine.
The administration of vasopressors strongly potentiates the neurological effects of intra-arterial contrast media.
Renal toxicity has been reported in patients with liver dysfunction who were given oral cholecystographic agents followed by intravascular contrast agents. Therefore, administration of intravascular contrast agents should be postponed in patients who have recently been given a cholecystographic contrast agent.
Contrast media may interfere with laboratory tests for bilirubin, proteins or inorganic substances (e.g. iron, copper, calcium, phosphate). These substances should not be assayed during the same day following the administration of contrast media.
In patients with pre-existing diabetic nephropathy administration of iopamidol can induce lactic acidosis if patients are concomitantly receiving a biguanide such as metformin. Treatment with the biguanide should be suspended 48 hours before iopamidol administration and can be resumed when renal function has returned to pre-examination level.
In patients receiving beta-blockers there is an elevated risk of more severe anaphylactoid reactions.
Following administration of iopamidol atypical adverse reactions e.g. erythema, fever and flu symptoms have been reported in patients treated with interleukin-2.
There is an elevated risk of seizures in patients with epilepsy or cerebral focal lesions treated with specific psychotropic drugs e.g. antipsychotic and analeptic drugs, tricyclic antidepressants and monoamine oxidase inhibitors. Such agents should be suspended- if possible - 48 hours before iopamidol administration and resumed 24 hours later.
Iopamidol should not be co administered with other drugs that are also known to prolong the QT interval because of the increased risk of cardiotoxicity.

Use during pregnancy and lactation
The safety of iopamidol injection during pregnancy has not been established. Since radiation exposure during pregnancy should be avoided anyway, regardless of whether a contrast agent is used or not, the benefit of X-ray examination has to be considered carefully. Apart from radiation exposure of the foetus, benefit-risk consideration for iodine-containing contrast agents should also take into account the sensitivity of the foetal thyroid towards iodine.
Iodine-containing x-ray contrast agents are excreted into the breast milk in low amounts. **It is recommended that they are administered to lactating women only if considered essential by the physician.** Breast-feeding should be stopped for 48 hours after administration of the contrast medium.

Undesirable Effects
a) Iopamidol may cause adverse reactions, which are generally mild or moderate and transient although rare severe and life-threatening reactions sometimes leading to death have been reported.
Adverse reactions often occur early but are sometimes delayed. Delayed intolerance reactions, most commonly pruritus and urticaria, have been reported up to several days post administration.
The most frequently observed adverse reactions have been nausea, vomiting, pain, burning sensation, hot flushes, a general feeling of warmth or cold and taste perversion. Others include localised pain at the injection site or in the lumbar, abdominal or chest region, headache, chills, fever, tremor, dizziness, rhinitis, oedema, dyspnoea, hypo or hypertension, tachycardia, angina pectoris, asthma, bronchospasm, confusion and convulsions.
Skin reactions may occur in the form of various types of rash, widespread erythema, diffuse blister formation, urticaria and pruritus. These reactions, which occur irrespective of the dose administered and the route of administration, may represent the first signs of incipient state of shock.
Anaphylaxis may manifest with symptoms including nausea, vomiting, diffuse erythema, mild localized or more diffuse angioedema, oedema of the tongue or larynx, laryngeal spasm or pain, dysphagia, sore throat and tightness, coughing, conjunctivitis, rhinitis, excessive sneezing, headache, fever, generalized heat sensation, sweating, asthenia, dizziness, pallor, dyspnoea, wheezing, bronchospasm, and moderate hypotension.

b) The spontaneously reported adverse reactions after intravascular administration are:
Blood and lymphatic system disorders: A few cases of thrombocytopenia have occurred.
Endocrine disorders: Hyperthyroidism may recur in patients previously treated for Graves' disease.
Metabolism and nutrition disorders: Acidosis, abnormalities in blood electrolyte values.
Nervous system disorders: Faintness, amnesia, confusion, alteration or loss of consciousness, coma, paraesthesia, dizziness, paresis and paralysis, tremors, convulsions, involuntary muscle contractions, somnolence.
Eye disorders: Vision disturbances, watery/itchy eyes, lacrimation, conjunctivitis, photophobia, transient cortical blindness.
Ear and labyrinth disorders: Impaired hearing, echoacousia, progressive transitory hearing loss or other auditory symptoms.
Cardiovascular disorders: Mainly after cardiovascular procedures/interventions: tachycardia, bradycardia, haemodynamic changes manifested with hypotension decreased systolic pressure, increase of left ventricular end diastolic pressure, hypertension, myocardial ischemia or infarction, heart failure, circulatory collapse, transient ischemic attack, ventricular arrhythmias, electrocardiographic changes including S-T segment depression, increased QT, increased R-R, T-wave amplitude.
Mostly after cardiac angiographic and coronary catheterisation procedures: cardiac rhythm disturbances such as bigeminy, extrasystoles, atrial fibrillation, ventricular tachycardia, and ventricular fibrillation, angina pectoris, chest pain, thrombophlebitis, cardiopulmonary arrest, arterial spasms, flushing, vasodilation, cyanosis.
Other cardiovascular reactions may occur as a consequence of the procedural hazard, these include haemorrhage or pseudoaneurysms at the puncture site, brachial plexus paralysis following axillary artery punctures, chest pain, arterial thrombosis, displacement of arterial plaques and serious thromboembolic events, venous thrombosis. Dissection of the coronary vessels and transient sinus arrest are rare complications.
Respiratory, thoracic and mediastinal disorders: Dyspnoea and respiratory distress, asthma, apnoea, throat constriction, coughing, sneezing, chest pain or tightness, bronchospasm, rhinitis, transient disturbance in respiratory rate, pulmonary oedema, laryngeal oedema, respiratory insufficiency or arrest.
Gastrointestinal disorders: Nausea, vomiting, anorexia, severe retching and choking, abdominal pain.
Skin and subcutaneous tissue disorders: Periorbital oedema, facial oedema, various rashes, urticaria, pruritus, flushing, erythema multiforme, pallor. Rarely, Stevens-Johnson syndrome has been reported.
Musculoskeletal, connective tissue and bone disorders: Muscle and lumbosacral weakness, musculoskeletal pain and muscle cramps.
Renal and urinary disorders: Transient changes in renal chemistry tests indicating renal impairment, acute renal failure, anuria, oliguria, urinary retention or incontinence, pain, haematuria.
General disorders and administration site conditions: Headache, fever, chills, excessive sweating, back spasm, malaise, warmth or cold sensation, vasovagal reactions, salivary gland secretion abnormalities, taste perversion, pain in the lumbar, abdominal or chest region, general pain. Local pain and non-inflammatory swelling may occur at the injection site. In the majority of cases it is due to extravasation of contrast medium. Reactions are usually transient and recover without sequelae, however, inflammation and even skin necrosis have been seen on very rare occasions.

c) An adverse reaction can develop independently of the quantity of contrast medium and way of administration, and a mild adverse reaction might be the first sign of a developing anaphylactic shock. Administration of the contrast medium must be discontinued immediately and if necessary specific treatment initiated.
Hypersensitivity reactions are more frequent in patients with an allergic disposition or who have shown hypersensitivity reactions during a previous examination with an iodinated contrast agent.
More severe reactions involving the cardiovascular system such as peripheral vasodilatation with pronounced hypotension, reflex tachycardia, angina, bronchospasm, dyspnoea, agitation, cyanosis and loss of consciousness (syncope), may require emergency treatment, appropriate resuscitative measures should be immediately available.
There is an increased risk of severe reactions in patients with severe cardiac disease, particularly in those with heart failure or coronary artery disease. The intravascular contrast medium injection can induce pulmonary oedema in patients with manifest heart failure, whereas contrast medium administration in pulmonary hypertension and valvular heart diseases can lead to pronounced haemodynamic changes. Ischaemic ECG changes and major arrythmias are most common in elderly patients and in those with pre-existing heart disease.

Overdose
Treatment of overdose is directed toward the immediate symptomatic therapy, support of all vital functions and the elimination of the contrast medium while keeping the patient well hydrated. Contrast agents may be removed by dialysis.

Pharmaceutical Particulars

List of Excipients
Trometamol, Hydrochloric acid, Sodium calcium edetate, Water for injections.

Incompatibilities
Many radiopaque contrast agents are incompatible in vitro with some antihistamines and many other drugs; therefore, no other pharmaceuticals should be admixed with contrast agents.

Special Precautions for Storage
Protect the solution from light and X-rays. Do not store above 25° C.
Store in the original package.

Instruction for Use/Handling
Scanlux® is intended for single use only; any unused portions should be discarded.
Discard if solution is not free from particulate matter.
The product should be introduced into the syringe immediately before use.
Iodinated contrast media can react with metallic surfaces containing copper (e.g. brass), therefore the use of equipment in which iopamidol comes into contact with such surfaces should be avoided.

Marketing Authorisation Holder
Sanochemia Pharmazeutika AG · Boltzmanngasse 11 · 1090 Vienna, Austria

SmPC dated
November 2011

Date of revision of the text
January 2013

Note: For further information please refer to SmPC

Prescription only, pharmacy only

SANOCHEMIA
Diagnostics International