SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Scanlux 300 mg I/ml, solution for injection

2 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 mPas

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection

Scanlux is a clear, colourless to pale yellow solution free from visible particles.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

This medicinal product is for diagnostic use only.
X-ray contrast media for peripheral arteriography and venography, angiocardiography, digital subtraction angiography, left ventriculography and coronary arteriography, computer tomography enhancement and urography.

4.2 Posology and method of administration

For intravenous or intra arterial use.

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.

The Special Warnings and Precautions for Use detailed in section 4.4 must be considered before administering this product. All patients should be observed for 20 to 30 minutes after the procedure, as most of the adverse events occur in this period.
In patients with suspected or known hypersensitivity to contrast media, sensitivity testing is not recommended, as severe or fatal reactions to contrast media are not predictable from sensitivity tests.
Caution during injection of contrast media is necessary to avoid extravasation.

As with all contrast media, the lowest dose necessary to obtain adequate visualisation should be used. The total volume that must not be exceeded is 250 ml. There are no special dosage requirements for elderly patients.

Non-ionic contrast media should not be allowed to remain in contact with blood in the syringe or intravascular catheters which should be flushed frequently to minimize the risk of clotting and thromboembolic events during angiographic techniques. Factors such as length of procedure, catheter and syringe material, underlying disease state, and concomitant medications may contribute to the development of thromboembolic events. Therefore, meticulous angiographic techniques are recommended including close attention to guide wire and catheter manipulation, use of manifold systems and/or three-way stopcocks, frequent catheter flushing with heparinized saline solutions, and minimizing the length of the procedure.

The following doses are recommended as a guide.

SCANLUX SOLUTION FOR INJECTION

Procedure	**Iopamidol solution for Injection product**	**Dosage**
Peripheral Arteriography	300 or 370 mg Iodine/ml	Adults 20-50 ml* Children**
Venography	300 mg Iodine/ml	Adults 20-50 ml Children**
Angiocardiography & left ventriculography	370 mg Iodine/ml	Adults 30-80 ml Children**
Coronary Arteriography	370 mg Iodine/ml	Adults 4-8 ml per artery*

		Children***
Digital Subtraction Angiography		
Intra-arterial injection	300 mg Iodine/ml	Adults 0.5-20 ml Children 0.25-0.375 ml/kg
Intra-venous injection	370 mg Iodine/ml	Adults 30-50 ml Children 0.5-0.75 ml/kg**
Left ventriculography	300 or 370 mg Iodine/ml	Adults 25 ml Children 0.5-0.75 ml/kg
Selective coronary arteriography by intra-arterial DSA	370 mg Iodine/ml	Adults 2-5 ml Children***
Computed Tomography Enhancement		
Brain Scanning	300 mg Iodine/ml	Adults 50-100 ml Children**
Whole Body Scanning	300 mg Iodine/ml	Adults 40-100 ml Children**
Intravenous Urography	300 or 370 mg Iodine/ml	Adults 40-80 ml In severe renal failure the usual high dose methods should be employed (up to 1.5 ml/kg) Children 1-2.5 ml/kg**

* Repeat as necessary.
** Proportional to the adult dose according to body size and age.
*** Procedure not normally applicable to children.

Method of administration

No other drugs or contrast media should be mixed with iopamidol solution for injection.

Peripheral arteriography and phlebography (venography)
Percutaneous injection into the appropriate blood vessel is used for visualisation of peripheral arteries and veins.

Computer tomography enhancement
Contrast enhancement for brain scans can be achieved between one and three minutes after i.v. injection. Scanlux injection is also used for total body

scanning examinations after i.v. administration as a bolus, as a drip infusion or by a combination of the two methods.

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.

4.3 Contraindications

Iopamidol is strictly contraindicated in patients with manifest hyperthyroidism.

Hypersensitivity to the active ingredient iopamidol and/or iodine or to any of the excipients listed in section 6.1.

4.4 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. Occasional severe reactions with fatal outcome have been reported. 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. Fluid intake should not be limited and any abnormalities of fluid or electrolyte balance should be corrected prior to use of this hypertonic solution.
As experience shows that warmed contrast media are better tolerated, the contrast medium should be warmed up to body temperature before administration.

Care should be exercised in patients with moderate to severe impairment of renal function. Pre-existing renal impairment may predispose to acute renal dysfunction following contrast media administration.
In patients with impairment of renal function, the administration of potentially nephrotoxic drugs should be avoided until the contrast medium is completely excreted. In such patients, renal function parameters should be monitored after the procedure. Further administration of contrast media should be postponed until renal function has returned to its previous level.

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.
Patients on dialysis may receive contrast media such as iopamidol, which can be removed without difficulty by dialysis.
The presence of renal damage in diabetic patients is one of the factors predisposing to acute renal impairment following intravascular contrast media administration. This may precipitate lactic acidosis in patients who are taking biguanides (see section 4.5). The risk associated with a particular investigation may be increased by conditions such as advanced arteriosclerosis and hypertension.

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.
Great caution should be paid when injecting the contrast medium into the heart chambers, especially in cyanotic neonates with pulmonary hypertension and impaired cardiac function.
During intracardiac and/or coronary arteriography, ventricular arrhythmias may infrequently occur.

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. 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.

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.

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.
Iopamidol should be administered with caution in patients with symptomatic cerebrovascular diseases, recent stroke, or frequent TIA, altered permeability of the blood-brain barrier, increased intracranial pressure, suspicion of intracranial tumor, abscess or hematoma/hemorrhage, history of convulsive disorder, alcoholism.

Use of this product may interfere with tests for thyroid function.

In patients scheduled for thyroid examination and/or treatment with a radioactive iodine tracer, iodine update in the thyroid gland will be reduced for several days, sometimes up to 2 weeks after dosing with an iodinated contrast medium that is eliminated through the kidneys.

Caution should be exercised in performing iodinated contrast-enhanced examinations in patients with, or with suspicion of, hyperthyroidism or autonomously functioning thyroid nodule(s), as thyroid storms have been reported following administration of iodinated contrast media. It is possible that hyperthyroidism may recur in patients previously treated for Graves' disease. In patients with hyperthyroidism, the radiological examination should be performed only if thought necessary by the physician.

Patients with phaeochromocytoma can develop severe hypertensive crises following intravascular iopamidol administration. Premedication with α-receptor blockers is recommended.

Patients with paraproteinaemia of Waldenström, with multiple myeloma or severely compromised hepatic and renal impairment are also more at risk: in these cases adequate hydration is recommended after contrast medium 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. After the administration of the contrast medium, competent personnel, drugs and equipment for emergency resuscitation must be available. Diagnostic procedures which involve the use of any radiopaque medium should be carried out under the direction of personnel with the prerequisite training and with a thorough knowledge of the particular procedure to be performed. Appropriate facilities should be available for coping with any complication of the procedure, as well as for emergency treatment of severe reaction to the contrast medium itself.

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 20-30 minutes 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.

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.

Vasospasm and subsequent cerebral ischemic phenomena may be caused by intra-arterial injections of contrast media.

Severe cutaneous adverse reactions
Severe cutaneous adverse reactions (SCARs), such Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (Lyell's syndrome or TEN) and acute generalised exanthematous pustulosis (AGEP), which can be life threatening, have been reported in patients administered Scanlux (see section 4.8, undesirable effects). At the time of initiation, patients should be advised of the signs and symptoms and monitored closely for severe skin reactions. If signs and symptoms suggestive of these reactions appear, further use of Scanlux should be withheld. If the patient has developed a severe cutaneous adverse reaction with the use of Scanlux, Scanlux must not be re-administered in this patient at any time.

No other drugs or contrast media should be mixed with iopamidol solution for injection (see section 6.2).

This medicinal product contains less than 1 mmol of sodium (23 mg) per maximum 250 ml dose, i.e. essentially "sodium-free".

Use in Special Populations
Newborns, children
Infants (age<1year), and especially newborns are particularly susceptible to electrolyte imbalances and haemodynamic alterations. Care should be taken regarding the dosage to be used, the details of the procedure, and the patient's status
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.

Elderly
The elderly are at special risk of reactions due to reduced physiological functions, especially when high dosage of contrast medium is used. Myocardial ischemia, major arrhythmias and premature ventricular complexes are more likely to occur in these patients. The probability of acute renal insufficiency is higher in these patients

Women of child-bearing potential
Appropriate investigations and measures should be taken when exposing women of childbearing potential to any X-ray examination, whether with or without contrast medium.

4.5 Interaction 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.

To prevent onset of lactic acidosis in diabetic patients under treatment with oral anti-diabetic agents of the biguanide class, biguanides should be stopped 48 hours before the administration of the contrast medium and re-instated only after renal function has been demonstrated to have returned to pre-examination values. (see section 4.4).

In patients receiving beta-blockers there is an elevated risk of more severe anaphylactoid reactions.
Cardiac and/or hypertensive patients under treatment with diuretics, ACE-inhibitors, and/or beta-blocking agents are at higher risk of adverse reactions when administered iodinated contrast media.

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.

4.6 Fertility, 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.

4.7 Effects on ability to drive and use machines

There is no known effect on the ability to drive and operate machines. However, because of the risk of early reactions, driving or operating machinery is not advisable for one hour following the last injection.

4.8 Undesirable effects

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.

Following intravascular administration, in most cases reactions occur within minutes of dosage. However, delayed reactions, usually involving skin, may occur, mostly within 2-3 days, more rarely within 7 days, after the administration of the contrast medium.

Anaphylaxis (anaphylactoid reactions/hypersensitivity) may manifest with: mild localized or more diffuse angioneurotic oedema, tongue oedema, laryngospasm or laryngeal oedema, dysphagia, pharyngitis and throat tightness, pharyngolaryngeal pain, cough, conjunctivitis, rhinitis, sneezing, feeling hot, sweating increased, asthenia, dizziness, pallor, dyspnoea, wheezing, bronchospasm, and moderate hypotension. Skin reactions may occur in the form of various types of rash, diffuse erythema, diffuse blisters, 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. Administration of the contrast medium must be discontinued immediately and – if necessary – specific treatment initiated via a venous access. More severe reactions involving the cardiovascular system such as vasodilatation with pronounced hypotension, tachycardia, dyspnoea, agitation, cyanosis and loss of consciousness (syncope) may require emergency treatment. 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.

Injection site pain and swelling may occur. On very rare occasions extravasation of contrast medium led to inflammation (manifested with local erythema, oedema and blisters), skin necrosis and compartment syndrome.

As with other iodinated contrast media, very rare cases of mucocutaneous syndromes, including Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell syndrome) and erythema multiforme, have been reported following the administration of Iopamidol.

Severe cutaneous adverse reactions (SCARs), including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and acute generalized exanthematous pustulosis (AGEP) have been reported in association with Scanlux administration (see section 4.4).

In clinical trials, the most commonly reported adverse reactions are headache (1.5 %), nausea (1.2 %) and
feeling hot (3.5%) after intravascular administration.
The adverse reactions reported in clinical trials among 2,680 adult subjects and 35 paediatric patients, and
from post marketing surveillance are presented in the tables below by frequency and classified by MedDRA
system organ classes.
Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.
Adult patients involved in clinical trials with intravascular administration of Iopamidol were 2,548, of whom 1,597 with intra-arterial and 951 with intravenous administration.

System Organ Class	Adverse Reactions			
	Clinical Trials			Post-marketing surveillance
	Common (≥1/100 to <1/10)	Uncommon (≥1/1,000 to <1/100)	Rare (≥1/10,000 to <1/1,000)	Frequency unknown*
Blood and lymphatic system disorders				Thrombocytopenia
immune system disorders				Anaphylaxis, Anaphylactoid reaction
Psychiatric disorders			Confusional state	
Nervous system disorders	Headache	Dizziness, Taste alteration	Paraesthesia	Coma, Transient ischaemic attack, Syncope, Depressed level of consciousness or loss of consciousness, Convulsion, Hemiplegia
Eye disorders				Blindness

				transient, Visual disturbance, Conjunctivitis, Photophobia
Cardiac disorders		Cardiac dysrhythmias such as extrasystoles, atrial fibrillation, ventricular tachycardia and ventricular fibrillation**	Bradycardia	Myocardial ischaemia or infarction, Cardiac failure, Cardio-respiratory arrest, Tachycardia, Kounis syndrome
Vascular disorders		Hypotension, Hypertension, Flushing		Circulatory collapse or shock
Respiratory, thoracic and mediastinal disorders			Pulmonary oedema, Asthma, Bronchospasm	Respiratory arrest, Respiratory failure, Acute respiratory distress syndrome, Respiratory distress, Apnoea, Laryngeal oedema, Dyspnoea
Gastrointestinal disorders	Nausea	Vomiting, Diarrhea, Abdominal pain, Dry mouth		Salivary hypersecretion, Salivary gland enlargement
Skin and subcutaneous tissue disorders		Rash, Urticaria, Pruritus, Erythema, Sweating increased		Face oedema, Acute generalised exanthematous pustulosis (AGEP)
Musculoskeletal and connective tissue disorders		Back pain	Muscle spasms	Musculoskeletal pain, Muscular weakness
Renal and urinary disorders		Acute renal failure		
General disorders and administration site conditions	Feeling hot	Chest pain, Injection site pain, Pyrexia, Feeling cold		Rigors, Pain, Malaise
Investigations		Blood creatinine		Electrocardiogram change including

		increased		ST segment depression

* Since the reactions were not observed during clinical trials with 2,548 patients, best estimate is that their relative occurrence is rare (≥1/10,000 to <1/1000). The most appropriate MedDRA term is used to describe a certain reaction and its symptoms and related conditions.
** Cardiac dysrhythmias may occur mostly after cardiac angiographic and coronary catheterization procedures

In addition, the following adverse events can occur with unknown frequency:

Metabolism and nutrition disorders: Acidosis, abnormalities in blood electrolyte values.

Nervous system disorders: amnesia, paresis and paralysis, tremors, somnolence.

Eye disorders: watery/itchy eyes, lacrimation.

Ear and labyrinth disorders: Impaired hearing, echoacousia, progressive transitory hearing loss or other auditory symptoms.

Gastrointestinal disorders: Anorexia, severe retching and choking.

Renal and urinary disorders: Transient changes in renal chemistry tests indicating renal impairment, anuria, oliguria, urinary retention or incontinence, pain, haematuria.

Mainly after cardiovascular procedures/interventions: haemodynamic changes manifested with hypotension decreased systolic pressure, increase of left ventricular end diastolic pressure, transient ischemic attack, electrocardiographic changes including S-T segment depression, increased QT, increased R-R, T-wave amplitude. Mostly after cardiac angiographic and coronary catheterisation procedures: angina pectoris, 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, arterial thrombosis, displacement of arterial plaques and serious thromboembolic events, venous thrombosis. Dissection of the coronary vessels and transient sinus arrest are rare complications.

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 arrhythmias are most common in elderly patients and in those with pre-existing heart disease.

Paediatric patients
The Iopamidol safety profile is similar in children and adults.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard.

4.9 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.

Dosages exceeding the specific package insert dose are not recommended, as they might lead to life-threatening adverse effects. If needed, hemodialysis can be used to eliminate iopamidol from the body. Treatment of overdosage is directed toward the support of all vital functions and prompt institution of symptomatic therapy.

In the event of accidental intravascular overdose in humans, the water and electrolyte losses must be compensated by infusion. Renal function should be monitored for at least three days

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

ATC code: V08AB04

Iopamidol is a second generation, non-ionic radiographic contrast medium that is stable in solution. Because of its non-ionic character, it lacks charged particles and is lower in osmolality than ionic agents of equivalent iodine concentration. Results of clinical and animal studies have indicated that Iopamidol causes less disturbance of cardiac function than do ionic contrast agents.

There is no evidence of teratogenic effects in rats or rabbits and no evidence of mutagenicity in the micronucleus test. However, there is evidence that, in common with all other iodinated contrast agents, Iopamidol Injection is able to produce a synergistic cytotoxicity in the presence of X-radiation. Chromosomal injury in human lymphocytes has been described in-vitro and in-vivo. The clinical significance of these observations is unclear.

Iopamidol Injection has no conventional clinical pharmacology, its intended action being a passive one of increasing the absorption of X-radiation by the tissues. It does, however, have a variety of incidental physiological, biochemical and haematological effects.

5.2 Pharmacokinetic properties

Absorption
Iopamidol is rapidly absorbed into the bloodstream from cerebrospinal fluid (CSF); following intrathecal administration, iopamidol appears in plasma within one hour and virtually all of the drug reaches the systemic circulation within 24 hours.

Distribution
Iopamidol injection is distributed throughout the extracellular fluid but does not enter cells. The volume of distribution is 0.28 l/kg and its plasma half-life is 121 minutes, which is prolonged in renal impairment. Iopamidol displays little tendency to bind to serum or plasma proteins. Animal studies indicate that iopamidol does not cross the blood-brain barrier to any significant extent following intravascular administration.

Metabolism
Iopamidol is excreted unchanged.

Excretion
Iopamidol is excreted mainly through the kidneys following intrathecal administration, and the drug is essentially undetectable in the plasma 48 hours later. In the absence of renal dysfunction, the cumulative urinary excretion for iopamidol, expressed as a percentage of administered intravenous dose, is approximately 35 to 40 percent at 60 minutes, 80 to 90 percent at 8 hours, and 90 percent or more in the 72 to 96 hour period after administration. In normal subjects, approximately 1 percent or less of the administered dose appears in cumulative 72 to 96 hour faecal specimens. No evidence of in vivo complement activation has been found in normal subjects.

5.3 Preclinical safety data

Intravenous LD_{50}-values in various animal species were determined to be approximately 15-35 times the maximum clinical dose.

Iopamidol did not show a teratogenic potential. In rats, dosages above 1.5g/kg iodine had embryotoxic effect and reduced the number of live foetuses and their weights. In rabbits, the weights of the foetuses were reduced at a dosage of 2.0g/kg iodine.

Iopamidol did not impair the fertility of rats and the peri- and postnatal development of their offspring.

However, in mice a reversible impairment of spermatogenesis was observed after a single dose of iopamidol.

Local tolerance:
The local pharmaceutical tolerance of Iopamidol (370mg Iodine/ml) was examined in rats after intramuscular injection into the aorta. In comparison

with ionic imaging agents the pharmaceutical tolerance of Iopamidol was equal or better.

Accidental paravascular injection can cause a local swelling, pain and erythema. Normally these reactions will abate without complications. Supporting the concerned extremity in a raised position and treating with cold compresses are favourable measures.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Trometamol
Hydrochloric acid
Sodium calcium edetate
Water for injections

6.2 Incompatibilities

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

6.3 Shelf life

2 years

After first opening, product should be used immediately.

6.4 Special precautions for storage

Protect the solution from light and X-rays

Do not store above 25ºC

Store in the original package

6.5 Nature and contents of container

Scanlux 300mg I/ml is available in 50 ml, 75 ml, 100 ml and 200 ml clear Type II glass bottles with bromobutyl stoppers, either individually or in the following pack sizes:

10 x 50 ml, 10 x 75 ml, 10 x 100 ml, 10 x 200 ml,
20 x 50 ml, 20 x 75 ml, 20 x 100 ml, 20 x 200 ml,
30 x 50 ml, 30 x 75 ml, 30 x 100 ml, 30 x 200 ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Scanlux 300mg I/ml Injection 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.

7 MARKETING AUTHORISATION HOLDER

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Landegger Straße 7
2491 Neufeld an der Leitha
Austria

8 MARKETING AUTHORISATION NUMBER(S)

PL 52910/0002

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