Lopitrast 370

Iopamidol

Compositions:
Lopitrast is presented as a clear colorless sterile injectable solution in the following concentrations: Lopitrast 370 (50 ml): Each 50 ml sterile solution contains 37.76 g of lopamidol equivalent to 370 mg of Iodine per ml. Lopitrast 370 (100 ml): Each 100 ml sterile solution contains 75.52 g of lopamidol equivalent to 370 mg of Iodine per ml.

Pharmacology:
lopamidol, an organic Iodine compound and used as a non-ionic water soluble radiographic contrast medium. Iopamidol blocks X-rays as they pass through the body, thereby allowing body structures not containing Iodine to be visualized. The degree of opacity produced by lopamidol is directly proportional to the total amount of the iodinated contrast agent in the path of the X-rays. The visualization of body structures is dependent upon the distribution and elimination of lopamidol.

Dosage And Administration:
Adult: NEURORADIOLOGY Lumber myelography: Lopitrast 370, 6-13 ml. Thoraco-cervical myelography: Lopitrast 370, 6-13 ml ANGIOGRAPHY Cerebral angiography: Lopitrast 370, 6-13 ml. Selective coronary arteriography: Lopitrast 370, 4-8 ml/artery. Peripheral arteriography: Lopitrast 370, 20-50 ml. Venography: Lopitrast 370, 24-60 ml. Angiocardiography: Lopitrast 370, 30-80 ml. Left ventriculography: Lopitrast 370, 30-80 ml. Percutaneous transfemoral / renal arteriography: Lopitrast 370, 30 ml. Selective renal arteriography: Lopitrast 370, 5-10 ml. Selective visceral arteriography: Hepatic angiography: Lopitrast 370, 70 ml. Coeliac angiography: Lopitrast 370, 40-70 ml. Superior mesenteric angiography: Lopitrast 370, 25-50 ml. Inferior mesenteric angiography: Lopitrast 370, 5-30 ml. Digital subtraction angiography: 30-50 ml (10-20ml/sec) of Lopitrast 370 i.v 25 ml (left ventricle), 2-5 ml (coronary arteries), 15 ml/sec of Lopitrast 370 i.a for cardiac imaging. UROGRAPHY: Lopitrast 370, 40-80 ml i.v up to 1.5 ml/kg in severe renal disease. OTHER DIAGNOSTIC PROCEDURES: Contrast enhancement in CT scanning: Lopitrast 370, 0.5-2.0 ml/ kg Children: 1-2.5 ml/kg Method of administration NEURORADIOLOGY Lumber myelography: A slow sub-arachnoid injection is made through a fine lumber puncture needle into one of the lower interspinous spaces (L3-L4 or L4-L5). Optimum contrast appears immediately after injections and films should be obtained promptly. Thoraco cervical myelography: Following a slow sub-arachnoid injection-the-patient should be-turned on his/her side and tilted 10°-20° head down under fluoroscopic control. In this manner it is possible to control movement of the contrast medium column into the dorsal region. If the cervical region is to be examined, the contrast medium should be run into the cervical region first, before the examination of the dorsal areas where it is progressively diluted. Lopitrast 370 may also be injected sub-occipitally or by lateral puncture technique. Care should be taken to ensure that the contrast medium does not move intracranially. It is generally recommended that in intrathecal use the patient should remain with a raised bed head and be kept well hydrated; following hydration it is preferable that the patient be allowed to be ambulatory. ANGIOGRAPHY Cerebral angiography: Any current technique is suitable for radiological visualization of the cerebral vasculature with Lopitrast 370 injection. Carotid and vertebral angiography, performed by catheterization or percutaneous injection techniques, require rapid injection which, if necessary, may be repeated. Peripheral arteriography and venography: Percutaneous injection into the appropriate blood vessel is used for visualization of peripheral arteries and veins. Angiocardiography, left ventriculography, selective coronary arteriography: Lopitrast 370 injection 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 in to any of the heart chambers, or injected into large vessel for immediate visualization. The contrast medium may also be administered during selective catheterization of the coronary arteries. Aortograpily: The contrast medium may be introduced directly or by intra-arterial injection for visualization of the aorta and its main branches. Selective visceral angiography: Visualization can be achieved by selective catheterization 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 catheterization to provide substrated images. Lopitrast 370 injected intravenously either centrally or peripherally is also recommended for use this modality. UROGRAPHY The contrast medium injected intravenously and rapidly eliminated through the kidneys. In patients with severe renal failure, high dose urography should be used. OTHER DIAGNOSTIC PROCEDURES Arthrography: Visualization of joint cavities and articular surfaces can be achieved either single or double contrast examination. Contrast enhancement in CT scanning: Contrast enhancement for brain scans can be achieved between one and three minutes after is. injection Lopitrast 370 are also be used for total body scanning examinations after i.v. administration as a bolus, as a drip infusion or by combination of the two methods.

Contraindications:
There are no definite or absolute contraindications to the use of Lopitrast with the possible exception of waldenstrom's macroglobulinemia, multiple myeloma and severe liver and kidney disease.

Warning And Precaution:
Lopitrast 370 should not be drawn into the syringe until immediately before use. The bottle, once opened, must be used immediately. In consideration of possible serious side effect, the use of organoiodinate contrast media should be limited to cases for which there is a precise need for radiographic contrast examination. This should be evaluated according to clinical status of the patient, in particular in relation to pathologies of the cardiovascular, urinary or hepatobiliary system. In particular contrast media designed for cardio angiography should be used in hospitals or clinics equipped and staffed for intensive care in emergencies. For other diagnostic procedures requiring the use of iodinised contrast media, in the public or institutions where such procedures take place, resuscitation equipment and therapeutic measures should be immediately available. When examining small children or babies, do not limit fluid intake before administering a hypertonic contrast solution. Also correct any existing water and electrolyte imbalance. X-ray examination of woman should also, if possible be conducted during the pre-ovulation phage of menstrual cycle, in patients scheduled for thyroid examination with a radioactive Iodine tracer, one must take into consideration that Iodine uptake in the thyroid gland will be reduced for several days (up to two weeks) after dosing with an iodinised contrast medium that is eliminated through kidney. Biguanide oral antidiabetic agents e.g. Metformin, are excreted unchanged through the kidneys. They therefore compete for excretion in the kidneys with contrast media and this could lead to reduction in kidney function. Patient with NIDDM who are taking Metformin or other biguanides should therefore be instructed not to take any doses of Metformin for 48 hours before and 48 hours after the X-ray examination.

Side Effects:
The use of organic Iodine compounds may cause untoward side effects and manifestations of anaphylaxis. The symptoms include nausea, vomiting, widespread erythema, generalized heat sensation, headache, coryza, fever, sweating, asthenia, dizziness, pallor, dyspnea, and moderate hypotension. Skin reactions occur in the form of various types of rash or diffuse blister formation. More severe reactions involving the cardiovascular system such as peripheral vasodilation with pronounced hypotension, tachycardia, dyspnea, agitation,

cyanosis and loss of consciousness, may require emergency treatment. During intra-cardiac and for coronary arteriography, ventricular arrhythmia may infrequently occur. Hyperthyroidism may recur in patients previously treated for graves’ disease.

Use in Pregnancy and Lactation:
Not well-defined

Drug Interaction:
Thyroid function test-use of Lopitrast 370 may interfere with tests or thyroid function. Biguanide oral anti-diabetic agents e.g. Metformin, are excreted unchanged through the kidneys They therefore compete for excretion in the kidneys with contrast media and this could lead to reduction in kidney function. Patient with NIDDM who are taking Metformin or other biguanides should therefore be instructed not to take any doses of Metformin for 48 hours before or 48 hours after the x-ray examination.

Overdosage:
Treatments of an overdose is directed toward the support of all vital functions and prompt institution of symptomatic therapy.

Storage:
Keep lopamidol away from light. Store below 30°C. Exceptionally crystallization of lopamidol injections can occur. It has been shown that such a phenomenon is caused by a damaged container and therefore the product should not be used in this case. The bottle once opened, must be used immediately. Any residue of contrast medium must be discarded.

Packing:
Lopitrast 370: (50 ml): Each glass bottle contains 37.76 g of lopamidol equivalent to 370 mg of Iodine per ml. Lopitrast 370: (100 ml): Each glass bottle contains 75.52 g of lopamidol equivalent to 370 mg of Iodine per ml.

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.