OMNIPAQUE EIRE prescribing information

PREScribing INFORMATION OMNIPAQUE™ (IOHEXOL)
Please refer to full national Summary of Products Characteristics (SPC) before prescribing.

PRESENTATION Aqueous solution for injection containing iohexol, a non-ionic, monomeric, triiodinated X-ray contrast medium, and available in five strengths containing either 140 mg, 180 mg, 240 mg, 300 mg or 350 mg iodine per ml.

INDICATIONS X-ray contrast medium for use in adults and children for angiography, urography, phlebography and CT-enhancement. Lumbar, thoracic, cervical myelography and computed tomography of the basal cisterns, following subarachnoid injection. Arthrography, endoscopic retrograde pancreatography, (ERP), endoscopic retrograde cholangiopancreatography (ERCP), herniography, hysterosalpingography, sialography and studies of the gastrointestinal tract.

DOSAGE AND ADMINISTRATIONS Adults & children: Dosage varies depending on the type of examination, age, weight, cardiac output and general condition of patient and the technique used (see SPC and package leaflet).

CONTRAINDICATIONS Manifest thyrotoxicosis. Hypersensitivity to the active substance or to any of the excipients.

WARNINGS AND PRECAUTIONS Allergy, asthma, or previous reactions to contrast media are risk factors for developing hypersensitivity reactions/anaphylactic reactions. Necessary drugs and equipment must be available for immediate treatment, should a serious reaction occur. It is advisable always to use an indwelling cannula or catheter for quick intravenous access throughout the entire X-ray procedure. After contrast medium administration the patient should be observed for at least 30 minutes, since the majority of serious side effects occur within this time. However, delayed reactions may occur. To prevent acute renal failure, special care should be exercised in patients with preexisting renal impairment, diabetes mellitus, paraproteinemia (myelomatosis and Waldenström’s macroglobulinemia), dehydrated patients, or patients who receive concurrent treatment with nephrotoxic drugs. To prevent lactic acidosis in diabetic patients treated with metformin, administration of metformin should be discontinued at the time of administration of contrast medium and withheld for 48 hours and reinstituted only after renal function has been re-evaluated and found to be normal. Patients with acute cerebral pathology, tumours or a history of epilepsy, alcoholics and drug addicts are predisposed to seizures. Adequate hydration should be assured. Young infants (age < 1 year) and especially neonates are susceptible to electrolyte disturbance and haemodynamic alterations. Patients with serious cardiac disease and pulmonary hypertension may develop haemodynamic changes or arrhythmias. Special care should be exercised in patients with hyperthyroidism. One should also be aware of the possibility of inducing transient hypothyroidism in premature infants receiving contrast media. Symptoms of myasthenia gravis may be aggravated. Extravasation of contrast media may on rare occasions give rise to local pain, and oedema, which usually recedes without sequelae. However, inflammation and even tissue necrosis have been seen. Elevating and cooling the affected site are recommended as routine measures. Surgical decompensation may be necessary in cases of compartment syndrome. Following myelography the patient should rest with the head and thorax elevated by 20° for one hour. Thereafter he/she may ambulate carefully but bending down must be avoided. The head and thorax should be kept elevated for the first 6 hours if remaining in bed. Patients suspected of having a low seizure threshold should be observed during this period. Outpatients should not be completely alone for the first 24 hours.

PREGNANCY AND LACTATION The safety of OMNIPAQUE in human pregnancy has not been established (see SPC). Omnipaque should not be used in pregnancy unless the benefit outweighs risk and it is considered essential by the physician. Contrast media are poorly excreted in human breast milk and minimal amounts are absorbed by the intestine. Harm to the nursing infant is therefore unlikely. Breast feeding may be continued normally when iodinated contrast media are given to the mother.

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developmental renal failure have been reported in premature infants, neonates and in other children after administration of iodinated contrast media. Premature infants are particularly sensitive to the effect of iodine. Transient hypothyroidism in a premature breast fed infant has been reported. The nursing mother was repeatedly exposed to Omnipaque. Especially in infants and small children, adequate hydration should be assured before and after contrast media administration. Nephrotoxic medication should be suspended. The age dependent reduced glomerular filtration rate in infants can also result in delayed excretion of contrast agents.

**INSTRUCTIONS FOR USE AND HANDLING** Like all parenteral products, OMNIPACQUE should be inspected visually for particulate contamination, discoloration and the integrity of the container prior to use. The product should be drawn into the syringe immediately before use. Containers are intended for single use only, any unused portions must be discarded. OMNIPAQUE may be warmed to body temperature (37°C) before administration.

**MARKETING AUTHORISATION HOLDER** GE Healthcare AS, Nyceveien 1-2, P.O. Box 4220 Nydalen, NO-0401 Oslo, Norway.

**CLASSIFICATION FOR SUPPLY** Subject to medical prescription (POM).

**MARKETING AUTHORISATION NUMBERS** PA 735/6/1, 2, 4, 8 and 13 (glass vials/bottles). PA 735/6/18, 20 and 23 (polypropylene bottles).

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