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, paraproteinemias (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 decompression 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.

UNDESIRABLE EFFECTS
General (applies to all uses of iodinated contrast media): Hypersensitivity reactions may occur irrespective of the dose and mode of administration and mild symptoms may represent the first signs of a serious anaphylactoid reaction/shock. An transient increase in S-creatinine is common after iodinated contrast media, contrast induced nephropathy may occur. Iodism or "iodide mumps" is a very rare complication of iodinated contrast media resulting in swelling and tenderness of the salivary glands for up to approximately 10 days after the examination. *Immune system disorders:* Rare: Hypersensitivity (including dyspnoea, rash, erythema, urticaria, pruritus, skin reaction, vasculitis, angioneurotic oedema, laryngeal oedema, laryngospasm, bronchospasm or non-cardiogenic pulmonary oedema). They may appear either immediately after the injection or up to a few days later. Not known: Anaphylactic/anaphylactoid reaction, anaphylactic/anaphylactoid shock. *Nervous system disorders:* Rare: Headache, Very rare: Dysgeusia (transient metallic taste), Not known: Syncope vasovagal. *Cardiac disorders:* Rare: Bradycardia. *Vascular disorders:* Very rare: Hypertension, hypotension. *Gastrointestinal disorders:* Uncommon: Nausea, Rare: Vomiting, Very rare: Diarrhoea, abdominal pain/discomfort, Not known: Salivary gland enlargement. *General disorders and administration site conditions:* Common: Feeling hot Rare: Pyrexia, Very rare: Shivering (chills). *Injury, poisoning and procedural complications:* Not known: Iodism. Intravascular use (intra-arterial and intravenous use): (*Please first read the section labelled "General").* The nature of the undesirable effects specifically seen during intraarterial use depends on the site of injection and dose given. Selective arteriographies and other procedures in which the contrast medium reaches a particular organ in high concentrations may be accompanied by complications in that particular organ. Immune system disorders: Not known: Severe pustular or exfoliative or bullous skin reactions. *Endocrine disorders:* Not known: Thyrotoxicosis, transient hypothyroidism. *Psychiatric disorders:* Not known: Confusion. *Nervous system disorders: R*are: Dizziness Very rare: Seizures, disturbance in consciousness, encephalopathy, stupor, sensory abnormalities (including hypoaesthesia), paraesthesia, tremor. Not known: Transient motor dysfunction (including speech disorder, aphasia, dysarthria), transient memory loss, disorientation, coma and retrograde amnesia. *Eye disorders:* Not known: Transient cortical blindness. *Ear and labyrinth disorders:* Not known: Transient hearing loss *Cardiac disorders: R*are: Arrhythmia (including bradycardia, tachycardia). Very rare: myocardial infarction, Not known: Severe cardiac complications (including cardiac arrest, cardio-respiratory arrest), spasm of coronary arteries, chest pain. *Vascular disorders:* Very rare: Flushing, Not known: Shock, arterial spasm, ischaemia, thrombophlebitis and thrombosis. *Respiratory, thoracic and mediastinal disorders:* Rare: Cough, Very rare: Dyspnoea, non-cardiogenic pulmonary oedema, Not known: Severe respiratory symptoms and signs, bronchospasm, laryngospasm, asthma attack. *Gastrointestinal disorders: Rare: Diarrhoea,* Not known: Aggravation of pancreatitis, acute pancreatitis. *Skin and subcutaneous tissue disorders:* Not known: Bullous dermatitis, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug rash with eosinophilia and systemic symptoms, psoriasis flare-up. *Musculoskeletal and connective tissue disorders:* Not known: Arthralgia. *Renal and urinary disorders:* Rare: Impairment of renal function including acute renal failure. *General disorders and administration site conditions:* Common: Feeling hot, Uncommon: Pain and discomfort, Rare:

Asthenic conditions (including malaise, fatigue), Not known: Administration site reactions, including extravasation, back pain. Intrathecal use: (*Please first read the section labelled "General").* Undesirable effects following intrathecal use may be delayed and present some hours or even days after the procedure. The frequency is similar to lumbar puncture alone. Headache, nausea, vomiting or dizziness may largely be attributed to pressure loss in the sub-arachnoid space resulting from leakage at the puncture site. Excessive removal of cerebrospinal fluid should be avoided in order to minimise pressure loss. *Psychiatric disorders:* Not known: Confusion. *Nervous system disorders: V*ery common: Headache (may be severe and prolonged), Uncommon: Aseptic meningitis (including chemical meningitis), Rare: Seizures, dizziness, Not known: Electroencephalogram abnormal, meningism, transient contrast-induced encephalopathy including transient memory loss, coma, stupor and retrograde amnesia, motor dysfunction (including speech disorder, aphasia, dysarthria), paraesthesia, hypoesthesia and sensory disturbance. *Eye disorders:* Not known: Transient cortical blindness, photophobia. *Ear and labyrinth disorders:* Not known: Transient hearing loss. *Gastrointestinal disorders:* Common: Nausea, vomiting. *Musculoskeletal and connective tissue disorders:* Rare: Neck pain, back pain, Not known: Muscle spasm. *General disorders and administration site conditions:* Rare: Pain in extremity, Not known: Administration site conditions. Use in Body Cavities: (*Please first read the section labelled "General"). Endoscopic Retrograde Cholangiopancreatography (ERCP) - Gastrointestinal disorders:* Common: Pancreatitis, blood amylase increased. *Oral use* - G*astrointestinal disorders:* Very common: Diarrhoea, Common: Nausea, vomiting, Uncommon: Abdominal pain. *Hysterosalpingography (HSG) - Gastrointestinal disorders:* Very common: Lower abdominal pain. *Arthrography - Musculoskeletal and connective tissue disorders:* Not known: Arthritis. *General disorders and administration site conditions:* Very common: Pain. *Herniography - General disorders and administration site conditions:* Not known: Post procedural pain. Thrombo-embolic complications have been reported in connection with contrast-enhanced angiography of coronary, cerebral, renal and peripheral arteries. The contrast agent may have contributed to the complications. Cardiac complications including acute myocardial infarction have been reported during or after contrast-enhanced coronary angiography. Elderly patients or patients with severe coronary artery disease, unstable angina pectoris and left ventricular dysfunction had a higher risk. In very rare occasions the contrast medium may cross the blood-brain barrier resulting in uptake of contrast medium in the cerebral cortex that may cause neurological reactions. They may include convulsions, transient motor or sensory disturbances, transient confusion, transient memory loss, and encephalopathy. Anaphylactoid reaction and anaphylactoid shock may lead to profound hypotension and related symptoms and signs like hypoxic encephalopathy, renal and hepatic failure. In several cases, extravasation of contrast media has caused local pain and oedema, which usually receded without sequelae. Inflammation, tissue necrosis and compartment syndrome have occurred. Paediatric patients: Transient hypothyroidism has 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, OMNIPAQUE should be inspected visually for particulate contamination, discolouration 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, Nycoveien 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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