PRESCRIBING INFORMATION OMNIPAQUE™ (iohexol)

Indications and approvals may vary in different countries. Please refer to the local Summary of Product Characteristics [SPC] bef ore prescribing. Further information available on request. **PRESENTATION:** Aqueous solution for injection containing iohexol, a non-ionic, monomeric, triiodinated X-ray contrast medium, and available in two strengths containing 300 mg and 350 mg iodine per ml. **INDICATIONS:** X-ray contrast medium for use in adults and children for cardioangiography, arteriography, 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:** Hypersensitivity to the active substance or to any of the excipients. Manifest thyrotoxicosis. History of serious reaction to OMNIPAQUE. **WARNINGS AND PRECAUTIONS:** Allergy, asthma, or previous reactions to iodinated contrast media are risk factors for developing anaphylactoid reactions or other manifestations of hypersensitivity. Necessary drugs and equipment must be available for immediate treatment, should a serious reaction occur. It is dvisable 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. Particularcare is required in patients with severe disturbance of both renal and hepatic function as they may have significantly delayed contrast medium clearance. To prevent lactic acidosis in diabetic patients treated with metformin, admonistration 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 occosions give rise to local pain and oedema, which usually recedes without sequelae. However, inflamation 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 forst 6 hours if remaining in bed. patients suspected of having a low seizure threshold dhould be observed during this period. Outpatients should not be completely alone for the first 24 hours. A few patients have experienced a temporary hearing loss or even deafness after myelography. **PREGNANCY AND LACTATION:** The safety of OMNIPAQUE in human pregnancy has not been established (see SPC). The degree of excretion into human milk is not known. **UNDESIRABLE EFFECTS:** All routes of administration: Hypersensitivity reactions with mild respiratory or cutaneous symptoms or anaphylactic reactions with more severe manifestations. Anaphylactoid reactions may occur irrespective of the dose and mode od administration and mild symptoms of hypersensivity may represent the first signs of a serious reaction. Vagal reactions causing hypotension and bradycardia. headache. Abdominal discomfort/pain, nausea or vomiting, transient metallic taste. Iodism or “iodide mumps” resulting in swelling and tenderness of the salivary glands. Feeling of warmth, fever, rigors, hypertension. Intravascular use (Intraarterial and Intravenous use) Neurological reactions, including seizures or transient motor or sensory disturbances. Cortical blindness. Serious cardiac complications, including cardiac arrest, arrhythmia, depressed cardiac function or signs of ischaemia. A transient increase in S-creatinine, followed by renal failure in rare occasions. Distal pain or heat sensation in peripheral angiography. Transient ischaemia after injection into coronary, cerebral or renal arteries. Post phlebographic thrombophlebitis or thrombosis. Arthralgia. Severe respiratory symptoms and signs (including dyspnoea, bronchospasm, ryngopasm, non-cardiogenic pulmonary oedema) and cough. Thyrotoxicosis, flushing anf injection site reaction s may occur. Intrathecal use: Meningism or chemical meningitis. Photophobia. Transient motor or sensory dysfunction. Confusion. Paraesthesia. Seizure s. EEG changes. Local pain, cramping and pain in the lower limbs. Headache, nausea, vomiting or dizziness. Transient blindness, neck pain and injection site reactions may occur. Use in Body Cavities Endoscopic Retrograde Cholangiopancreatography (ERCP): Elevation of amylase levels, pancreatitis. Oral use: Gastrointestinal upset. Hysterosalpingography (HSG): Transient pain in the lower abdomen. Arthrography: Post procedural pain. Frank arthritis. Herniography: Mild postprocedural pain. **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. **ADDITIONAL INSTRUCTION FOR AUTOINJECTOR/PUMP:** The 500 ml contrast medium multi-dose bottles should only be used in connection with auto injectors/pumps approved for this volume. A single piercing procedure should be used. The line running from this auto injector/pump to the patient must be exchanged after each patient. The 500 ml bottles if not used immediately after opening must be used within 24 hours, at temperatures below 25°C.

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).

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