PRESCRIBING INFORMATION OMNIPAQUE™ (iohexol)
Please refer to full national Summary of Product Characteristics (SPC) before prescribing. Indications and approvals may vary in different countries. Further information available on request.

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

INDICATIONS For diagnostic use only. X-ray contrast medium for use in adults and children for urography, phlebography, i.v. DSA, CT, arteriography, cardioangiography and i.a. DSA. Myelography. For use in body cavities: Arthrography, ERP/ERCP, herniography, hysterosalpingography, sialography and use in the G-I tract. Contrast-enhanced mammography (CEM) in adults to evaluate and detect known or suspected lesions of the breast, as an adjunct to mammography (with or without ultrasound) or as an alternative to magnetic resonance imaging (MRI) when MRI is contraindicated or unavailable.

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.

WARNINGS AND PRECAUTIONS Hypersensitivity: Positive history of allergy, asthma, or untoward reactions to iodinated contrast media indicates a need for special caution. Application should be preceded by a medical history and a strict indication is required in patients with allergic diathesis and known hypersensitivity reactions. Patients with an increased risk of acute hypersensitivity reactions, a previous moderate or severe acute reaction to contrast agent, asthma or allergy requiring medical treatment, premedication with corticosteroids or antihistamines may be considered. However, premedication does not prevent severe reactions but may reduce their incidence and severity. Bronchial asthma patients are at increased risk of bronchospasm. Iodinated contrast media may provoke serious, life-threatening, fatal anaphylactic/ anaphylactoid reactions or other manifestations of hypersensitivity (See SPC for detail). In imminent state of shock, administration of contrast medium must be terminated immediately and specific intravenous treatment must be initiated. Patients using beta-adrenergic blocking agents, particularly asthmatic patients, may have a lower threshold for bronchospasm and are less responsive to treatment with beta agonists and adrenaline, which may necessitate the use of higher doses. Reactions usually occur within one hour following application however may also occur after hours or days, but are rarely life threatening. Coagulopathy: Catheter angiography with contrast media and numerous other factors during catheterization (see SPC for detail) may influence the development of thromboembolic events. *In vitro*, non-ionic contrast media have a weaker coagulation inhibiting effect than ionic contrast media. Care should be taken in patients with homocystinuria. (Risk for thromboembolism). Hydration: Assure hydration before and after administration, especially in infants and small children. If necessary, hydrate patient intravenously until excretion of contrast medium is complete, this applies especially to at risk patients (see SPC for detail) where water and electrolyte metabolism must be controlled and symptoms of a dropping serum calcium level must be taken care of. Due to risk of dehydration induced by diuretics, at first, water and electrolyte rehydration is necessary to limit risk of acute renal failure. Cardio-circulatory reactions: Patients with serious cardiac disease/cardio-circulatory disease and pulmonary hypertension may develop haemodynamic changes or arrhythmias. This is especially applicable following intracoronary, left and right ventricular application of contrast media. In elderly patients and patients with ischaemic cardiac diseases, reactions may occur. In cardiac insufficiency patients' pulmonary oedema may occur.
CNS disturbances: Patients with acute cerebral pathology, tumours or a history of epilepsy, alcoholics and drug addicts have increased risk for seizures and neurological reactions. Encephalopathy has been reported with the use of contrast media, such as iohexol. Contrast encephalopathy may manifest with symptoms and signs of neurological dysfunction (see SPC for detail). Symptoms usually occur within minutes to hours after administration of iohexol, and generally resolve within days. Factors which increase blood-brain barrier permeability will ease the transfer of contrast media to brain tissue and may lead to possible CNS reactions for instance encephalopathy. If contrast encephalopathy is suspected, administration of iohexol should be discontinued and appropriate medical management should be initiated. Application can aggravate neurological symptoms caused by metastases, degenerative or inflammatory processes. A few patients have experienced temporary hearing loss or even deafness. Patients with cerebrovascular diseases, previous stroke and transitory ischaemic attacks risk increased neurological complications following injection. Intra-arterial injection may induce vasospasm with resulting cerebral ischaemic phenomena. Renal reactions: Application may cause contrast induced nephropathy, impairment of renal function or acute renal failure. Increased risk in patients with pre-existing renal impairment and diabetes mellitus (see SPC for detail). Patients on haemodialysis may receive contrast media for radiological procedures. Correlation of time of injection with the haemodialysis session is unnecessary. Diabetic patients receiving metformin:
These patients are at risk of development of lactic acidosis after administration, particularly those with impaired renal function. To reduce risk of lactic acidosis, serum creatinine level should be measured prior to intravascular administration and the following precautions undertaken in the following circumstances: (1) Patients with eGFR equal or greater than 60 ml/min/1.73m^2 (CKD 1 and 2) can continue to take metformin normally. (2) Patients with eGFR 30-59 ml/min/1.73m^2 (CKD 3): - Patients receiving intravenous contrast medium with eGFR equal or greater than 45 ml/min /1.73m^2) can continue to take metformin normally. - In patients receiving intra-arterial contrast medium, and those receiving intravenous contrast medium with an eGFR between 30 and 44 ml/min/1.73m^2 metformin should be discontinued 48 hours before contrast medium and should only be restarted 48 hours after contrast medium if renal function has not deteriorated. (3) In patients with eGFR less than 30 ml/min/1.73m^2 (CKD 4 and 5) or with an intercurrent illness causing reduced liver function or hypoxia metformin is contraindicated and iodinated contrast media should be avoided. (4) In emergency patients in whom renal function is either impaired or unknown, the physician shall weigh out risk and benefit of an examination with a contrast medium. Metformin should be stopped from the time of contrast medium administration. After the procedure, the patient should be monitored for signs of lactic acidosis. The patient should be fully hydrated prior to and for 24 hours after contrast medium administration. Renal function, serum lactic acid and blood pH should be monitored, as well as the patient with regard to signs and symptoms of lactic acidosis. A pH <7.25 or a lactic acid level of >5 mmol/litre are indicative of lactic acidosis. Metformin should be restarted 48 hours after contrast medium if serum creatinine/eGFR is unchanged from the pre-imaging level.
Patients with disturbance of both hepatic and renal function (See SPC for detail). Care is required in patients with severe disturbance of both renal and hepatic function as they may have significantly delayed contrast medium clearance. Patients on haemodialysis may receive contrast media for radiological procedures. Correlation of time of contrast media injection with the haemodialysis session is unnecessary. Myasthenia gravis: Administration may aggravate symptoms of myasthenia gravis. Phaeochromocytoma: Patients with phaeochromocytoma undergoing interventional procedures, should be given alpha blockers as prophylaxis to avoid hypertensive crisis. Disturbed thyroid function: Free iodide in the solutions and iodide released by deiodination influences thyroid function and may induce hyperthyroidism or even thyrotoxic crisis in predisposed patients (see SPC for detail). These patients should have their thyroid function assessed before examination. Before administering, make sure the patient is not about to undergo thyroid scan, function tests or treatment with radioactive iodine, as administration of iodinated contrast agents interferes with hormone assays and iodine uptake by the thyroid gland or metastases from thyroid cancer until urinary iodine excretion returns to normal.

Thyroid function tests indicative of hypothyroidism or transient thyroid suppression have been reported following iodinated contrast media administration to adult and paediatric patients, including infants. Some patients were treated for hypothyroidism. See also section on Paediatric population. Anxiety conditions: A sedative may be administered in the case of marked anxiety. Sickle cell disease: Intravenous and intra-arterial injection may promote sickling in individuals homozygous for sickle cell disease. Further risk factors: Among patients with autoimmune diseases, serious vasculitis or Stevens Johnson-like syndromes have been observed. Severe vascular and neurological diseases, present especially in elderly patients, are risk factors for reactions. Extravasation: Contrast media may give rise to local pain, oedema and erythema, which usually recedes without sequelae. However, inflammation and tissue necrosis have been seen. Elevating and cooling the affected site is recommended as routine. Surgical decompression may be necessary in cases of compartment syndrome. Observation-time: Patients must be kept under close observation for 30 minutes following the last injection as the majority of severe reactions occur at this time. Intrathecal use: Following myelography the patient should rest for one hour with head and thorax elevated by 20°. Thereafter he/she may ambulate carefully but avoid bending down. 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 alone for the first 24 hours. Cerebral arteriography: In patients with advanced arteriosclerosis, severe hypertension, cardiac decompensation, old age, and previous cerebral thrombosis or embolism and migraine, cardiovascular reactions such as bradycardia and increases or decreases in blood pressure may occur more often. Arteriography: Injury of the artery, vein, aorta and adjacent organs, pleurocentesis, retroperitoneal bleeding, spinal cord injury and symptoms of paraplegia may occur. Paediatric population: Hypothyroidism or transient thyroid suppression may be observed after exposure to iodinated contrast media. Special attention should be paid to paediatric patients below 3 years of age because an incident underactive thyroid during early life may be harmful for motor, hearing, and cognitive development and may require transient T4 replacement therapy. The incidence of hypothyroidism in patients younger than 3 years of age exposed to iodinated contrast media has been reported between 1.3% and 15% depending on the age of the subjects and the dose of the iodinated contrast agent and is more commonly observed in neonates and premature infants. Neonates may also be exposed through the mother during pregnancy. Thyroid function should be evaluated in all paediatric patients younger than 3 years of age within 3 weeks following exposure to iodinated contrast media, especially in premature infants and neonates. If hypothyroidism is detected, thyroid function should be monitored as appropriate even when replacement treatment is given. Nephrotoxic medication should be suspended. The age dependent reduced glomerular filtration rate in infants can result in delayed excretion of contrast agents. Infants, age < 1 year, and neonates are especially susceptible to electrolyte disturbance and haemodynamic alterations. Contrast-enhanced mammography (CEM): Contrast-enhanced mammography results in higher patient exposure to ionizing radiation than standard mammography. Radiation dose depends on breast thickness, the type of mammographic device and the device's system settings. The overall CEM radiation dose remains under the threshold defined by international guidelines for mammography (below 3 mGy).

INTERACTION WITH OTHER MEDICINAL PRODUCTS See SPC for detail.

PREGNANCY AND LACTATION The safety of OMNIPAQUE in human pregnancy has not been established (see SPC for detail). OMNIPAQUE should not be used in pregnancy unless considered essential. Breast feeding may be continued normally when iodinated contrast media are given to the mother. Apart from avoidance of exposition to radiation, the sensitivity of the foetal thyroid gland to iodine should be taken into account when risk and benefit are evaluated.

ABILITY TO DRIVE AND USE MACHINES It is not advisable to drive a car or use machines for one hour after the last injection or for 24 hours following intrathecal procedure.

UNDESIRABLE EFFECTS All routes of administration: 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. Administration of the contrast medium must be discontinued immediately and, if necessary, specific therapy instituted via the vascular access. 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. Common: Feeling hot. Uncommon: Headache, nausea, hyperhidrosis, cold feeling, vasovagal reactions. Rare: Hypersensitivity (may be life-threatening or fatal), vomiting, abdominal pain, bradycardia, pyrexia (See SPC for detail). Intravascular use (Intraarterial and Intravenous use): Common: Transient changes in respiratory rate, respiratory distress. Uncommon: Acute kidney injury, pain and discomfort. Intrathecal use: 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. Very common: Headache (may be severe and prolonged). Common: Nausea, vomiting. Uncommon: Aseptic meningitis (including chemical meningitis. **Use in Body Cavities: Endoscopic Retrograde Cholangiopancreatography (ERCP):** Common: Elevation of amylase levels, pancreatitis. **Oral use:** Very common: Diarrhoea. Common: Nausea, vomiting. Uncommon: Abdominal pain. **Hysterosalpingography (HSG):** Very common: Lower abdominal pain. **Arthrography:** Very common: Pain. (Please see SPC in relation to other adverse events).

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. Vials and bottles up to 200 ml are intended for single use only; any unused portions must be discarded. OMNIPAQUE may be warmed to body temperature (37°C) before administration. For correct use of 500, 700 and 1000 mL multi-dose bottles, refer to full SPC. Multi-dose bottles must be used within 24 hours of opening.

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 NUMBER PL 00637/0034,0035,0036,0038.

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PRICE 350mgI/ml, 10x50ml: £208.01

Adverse events should be reported.
Reporting forms and information can be found at https://yellowcard.mhra.gov.uk.
Adverse events should also be reported to GE HealthCare at gpv.drugsafety@gehealthcare.com.