PRESCRIBING INFORMATION VISIPAQUE™ Injection (iodixanol)
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
An isotonic, aqueous solution containing iodixanol, a non-ionic, dimeric contrast medium, available in two strengths containing either 270 mg or 320 mg iodine per ml.

INDICATIONS
For diagnostic use only X-ray contrast medium for use in adults in cardioangiography, cerebral angiography (conventional), peripheral arteriography (conventional), abdominal angiography (i.a. DSA), urography, venography, CT enhancement, studies of the upper gastrointestinal tract, arthrography and hysterosalpingography (HSG) Lumbar, thoracic and cervical myelography in adults.
In children for cardioangiography, urography, CT enhancement and studies of the upper gastrointestinal tract.

DOSAGE AND ADMINISTRATION
Adults and children: Dosage varies depending on the type of examination, age, weight, cardiac output, general condition of patient and the technique used (see SPC and package leaflet). For correct use of 500 mL multi-dose bottles, refer to full SPC. Multi-dose bottles must be used within 24 hours of opening.

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

WARNINGS AND PRECAUTIONS
A positive history of allergy, asthma, or reaction to iodinated contrast media indicates need for special caution. Premedication with corticosteroids or H1 and H2 antagonists might be considered in these cases. Although the risk of serious reactions with VISIPAQUE is regarded as remote, iodinated contrast media may provoke serious life-threatening hypersensitivity reactions, including fatal anaphylactic reactions. Therefore the necessary drugs and equipment must be available for immediate treatment. Patients should be observed closely for at least 30 minutes following administration of contrast medium, however delayed reactions may occur. Advanced life support facilities should be readily available. Use of beta blockers may be a risk factor for anaphylactoid reactions and patients may present with atypical symptoms of hypersensitivity which may be misinterpreted as a vagal response. The use of beta-adrenergic blocking agents may lower the threshold for bronchospasm in asthmatic patients after contrast medium administration, and reduce the responsiveness of treatment with adrenaline. Non-ionic iodinated contrast media inhibit blood coagulation in vitro, less than ionic contrast media. When performing vascular catheterisation procedures one should pay meticulous attention to the angiographic technique and flush the catheter frequently (e.g. with heparinised saline) so as to minimize the risk of procedure-related thrombosis and embolism. Serious, rarely fatal, thromboembolic events causing, myocardial infarction and stroke have been reported during angio-cardiographic procedures with both ionic and non-ionic contrast media. Therefore, meticulous intravascular administration technique is necessary, particularly during angiographic procedures, to minimize thromboembolic events. There is a risk of thromboembolism in patients with homocystinuria. Ensure adequate hydration before and after examination especially in patients with multiple myeloma, renal dysfunction, diabetes mellitus, paraproteinemias, the elderly, children and infants. Care should be taken in patients with serious cardiac disease and pulmonary hypertension as they may develop hemodynamic changes or arrhythmias. Encephalopathy has been reported with the use of iodixanol. The product should be used with caution in patients with conditions that disrupt the integrity of the blood brain barrier (BBB), potentially leading to increased permeability of contrast media across the BBB and increasing risk of encephalopathy. In intravascular application, care should be taken in patients with acute stroke, or acute intracranial bleeding, in patients with altered blood brain barrier, cerebral oedema or acute demyelinisation. If contrast encephalopathy is suspected, administration of iodixanol should be discontinued and appropriate medical management should be initiated. Particular care is required in patients with severe disturbance of both renal and hepatic function as they may have significantly delayed contrast medium clearance. For haemodialysis patients, correlation of time of contrast media injection with the haemodialysis session is unnecessary. To prevent lactic acidosis in diabetic patients treated with metformin, the serum creatinine level should be measured in diabetic patients treated with metformin prior to intravascular administration of iodinated contrast media.
(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 eGRF 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 iodinated contrast media should be avoided. (4) In emergency cases where renal function is impaired or unknown, the physician should evaluate the risk/benefit of the contrast medium examination, and the following precautions should be implemented: Metformin should be stopped. The patient should be fully hydrated prior to contrast medium administration and for 24 hours afterwards. Renal function (e.g. serum creatinine), serum lactic acid and blood pH should be monitored. A pH< 7.25 or a lactic acid level of > 5 mmol/litre are indicative of lactic acidosis. The patient should be observed for symptoms of lactic acidosis. These include vomiting, somnolence, nausea, epigastric pain, anorexia, hyperpnoea, lethargy, diarrhoea and thirst. Special care should also be taken in patients with serious cardiac disease, pulmonary hypertension, arteriosclerosis, patients predisposed to seizures (acute cerebral pathology, tumours, epilepsy, alcoholics and drug addicts), and patients with myasthenia gravis or phaeochromocytoma.

Patients with manifest but not yet diagnosed hyperthyroidism, patients with latent hyperthyroidism (e.g., nodular goitre) and patients with functional autonomy (often e.g. elderly patients, especially in regions with iodine deficiency) are at higher risk of acute thyrotoxicosis after use of iodinated contrast media. The additional risk should be evaluated in such patients before use of an iodinated contrast medium. 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. 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 following exposure to iodinated contrast media. If hypothyroidism is detected, the need for treatment should be considered and thyroid function should be monitored until normalized. After intrathecal use the patient should rest with head and thorax elevated for one hour and outpatients should not be alone for 24 hours.
All iodinated contrast media may interfere with laboratory tests for thyroid function, bilirubin, proteins, or inorganic substances (e.g. iron, copper, calcium, and phosphate). An increased risk of delayed reactions (flu-like or skin reactions) has been associated with patients treated with interleukin-2 up to two weeks previously. Consideration should be taken when administrating this product to a patient on a controlled sodium diet.

PREGNANCY AND LACTATION
The safety of VISIPAQUE in pregnancy has not been established. Contrast media are poorly excreted in breast milk and minimal amounts are absorbed by the intestine. Breast feeding may be continued normally. In neonates who have been exposed to iodinated contrast media in utero, it is recommended to monitor thyroid function, refer to full SPC.

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

UNDESIRABLE EFFECTS
Undesirable effects are usually mild to moderate, and transient in nature. Serious reactions and fatalities are only seen on very rare occasions. Serious reactions as well as fatalities are only seen on very rare occasions, these may include acute-on-chronic renal failure, acute renal failure, anaphylactic or anaphylactoid shock, hypersensitivity reaction followed by cardiac reactions (Kounis' syndrome), cardiac or cardio-respiratory arrest and myocardial infarction.
Hypersensitivity may present as respiratory or cutaneous symptoms like dyspnoea, rash, erythema, urticaria, pruritus, skin reactions, angioneurotic oedema, hypotension, fever, laryngeal oedema, bronchospasm or pulmonary oedema. In patients with autoimmune diseases cases of vasculitis and SJS-like syndrome were observed. They may occur immediately after injection or up to a few days later, irrespective of dose, and mild symptoms may be the first signs of serious anaphylactoid reaction/shock.
Intravascular use: Uncommon: hypersensitivity, headache, flushing, nausea, vomiting, rash or drug eruption , pruritus, urticaria, acute kidney injury or nephropathy toxic (CIN), feeling hot, chest pain. Rare: dizziness, sensory abnormalities including taste disturbance, paraesthesia, parosmia, arrhythmia (including bradycardia, tachycardia), myocardial infarction, hypotension, cough, sneezing, erythema pain and discomfort, shivering (chills), pyrexia, administration site reactions including extravasation, feeling cold. Very rare: agitation, anxiety, cerebrovascular accident, amnesia, syncope, cardiac arrest, palpitation, cortical blindness (transient), transient visual impairment (including diplopia, blurred vision), eyelid oedema, hypertension, ischaemia, dyspnoea, throat irritation, laryngeal oedema, pharyngeal oedema, abdominal pain/discomfort, diarrhoea, angioedema, hyperhidrosis, back pain, muscle spasm, asthenic conditions (e.g. malaise, fatigue), face oedema, localised oedema.
Frequency unknown: thrombocytopenia, anaphylactic/anaphylactoid shock, anaphylactic/anaphylactoid reaction including life-threatening or fatal anaphylaxis, hyperthyroidism, transient hypothyroidism, confusional state, coma, disturbance in consciousness, seizures, transient contrast-induced encephalopathy caused by extravasation of contrast media, which can manifest as sensory, motor or global neurological dysfunction (including hallucination, paralysis, paresis, disorientation, transient speech disorder, aphasia, dysarthria), , Cardio-respiratory arrest, ventricular hypokinesia, myocardial ischaemia, conduction abnormalities, coronary artery thrombosis, angina pectoris, spasm of coronary arteries, arterial spasm, thrombosis, thrombophlebitis, shock, Non-cardiogenic pulmonary oedema, respiratory arrest, respiratory failure, bronchospasm, throat tightness, acute or aggravated pancreatitis, salivary gland enlargement, bullous dermatitis or exfoliative, Stevens-Johnson syndrome, erythema multiforme, toxic epidermal necrolysis, acute generalised exanthematous pustulosis, drug rash with eosinophilia and systemic symptoms, dermatitis allergic, increased blood creatinine, swelling,arthralgia, iodism.
Intrathecal use: Uncommon: headache (may be severe and lasting), vomiting. Frequency unknown: hypersensitivity including anaphylactic/anaphylactoid reactions, dizziness, transient contrast-induced encephalopathy caused by extravasation of contrast media, which can manifest as sensory, motor or global eurological dysfunction including amnesia, hallucination, confusional state, paralysis, paresis, disorientation, aphasia, speech disorder, nausea, muscle spasm, shivering, injection site reaction.
Hysterosalpingography: Very common: abdominal pain, vaginal haemorrhage. Common: headache, nausea, pyrexia. Frequency unknown: hypersensitivity, vomiting, shivering, injection site reaction.
Arthrography: Common: injection site pain. Frequency unknown: hypersensitivity including anaphylactic/anaphylactoid reactions, shivering.
GI tract: Common: diarrhoea, abdominal pain, nausea. Uncommon: vomiting. Frequency unknown: hypersensitivity including anaphylactic/anaphylactoid reactions, shivering.

OVERDOSE
In the event of accidental overdosing, the water and electrolyte losses must be compensated by infusion. Renal function should be monitored for at least the next 3 days. If needed, haemodialysis may be used to remove iodixanol from the patient's system. Treatment of overdose is symptomatic.

PHARMACODYNAMIC PROPERTIES
ATC code: V08A B09.
In 64 diabetic patients with serum creatinine levels of 115 - 308 µmol/L, VISIPAQUE use resulted in 3% of patients experiencing a rise in creatinine of ≥ 44.2 µmol/L and 0% of the patients with a rise of ≥ 88.4 µmol/L. The release of enzymes (alkaline phosphatase and N-acetyl-β-glucosaminidase) from the proximal tubular cells is less than after injections of non-ionic monomeric contrast media and the same trend is seen compared to ionic dimeric contrast media. VISIPAQUE is also well tolerated by the kidney.

INSTRUCTIONS FOR USE AND HANDLING
Do not mix with other medicinal products. Like all parenteral products, VISIPAQUE should be inspected visually for particulate matter, 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. VISIPAQUE may be warmed to body temperature (37°C) before administration.

MARKETING AUTHORISATION HOLDER
GE Healthcare AS, Nycoveien 1, 0485 Oslo, Norway.

CLASSIFICATION FOR SUPPLY
Subject to medical prescription (POM).

MARKETING AUTHORISATION NUMBERS
PL 0637/0018-19 (Glass vials/bottles and polypropylene bottles with stopper and screw cap).

DATE OF REVISION OF TEXT
Date of revision of text: (February 2026), based on SmPC dated (November 2025).

PRICE
320mgI/ml, 10x50ml: £208.22

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