Prescribing Information

VISIPAQUE™ iodixanol

Indications and approvals may vary in different countries. Please refer to the local Summary of Product Characteristics [SPC] before prescribing. 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 This medicinal product is for diagnostic use only. X-ray contrast medium for use in adults for cardioangiography, cerebral angiography (conventional and i.a.DSA), peripheral arteriography (conventional and i.a.DSA), abdominal angi ography (i.a.DSA), urography, venography and CT-enhancement.

DOSAGE AND ADMINISTRATION Adults: 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).

CONTRA-INDICATIONS Hypersensitivity to the active substance or to any of the excipients. Manifest thyrotoxicosis. History of serious hypersensitivity reaction to Visipaque. PRECAUTIONS, WARNINGS, ETC-Not approved for intrathecal use. 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 should be considered in these cases. Although the risk of serious reactions with Visipaque is regarded as low, iodinated contrast media may provoke serious, life-threatening, fatal anaphylactic/ anaphylactoid reactions or other manifestations of hypersensitivity. Therefore the necessary drugs and equipment must be available for immediate treatment. Patients should be observed for at least 30 minutes following administration of contrast medium, however delayed reactions may occur. Non-ionic contrast media have less effect on the coagulation system in vitro, compared to ionic contrast media. When performing vascular catheterization procedures one should pay meticulous attention to the angiographic technique and flush the catheter frequently (eg. with heparinised saline) so as to minimize the risk of procedure-related thrombosis and embolism. Ensure adequate hydration before and after examination especially in patients with renal dysfunction, diabetes mellitus, paraproteinemias, the elderly, or after major surgery. Special care should also be taken in patients with hyperthyroidism, serious cardiac disease, pulmonary hypertension, patients predisposed to seizures (acute cerebral pathology, tumours, epilepsy, alcoholics and drug addicts), and patients with myasthenia gravis or phaeochromocytoma. Particular care is required in patients with severe disturbance of both renal and hepatic function as they may have significantly delayed contrast medium clearance. All iodinated contrast media may interfere with laboratory tests for thyroid function, bilirubin, proteins, or inorganic substances (e.g. iron, copper, calcium, and phosphate). To prevent lactic acidosis, serum creatinine level should be measured in diabetic patients treated with metformin prior to intravascular administration of iodinated contrast medium. Normal serum creatinine/renal function: Administration of metformin should be stopped at the time of administration of contrast medium and not resumed for 48 hours or until renal function/serum creatinine is normal. The timing of this should be amended based upon serum creatinine/renal function levels. (Refer to SPC). 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.

The safety of Visipaque in pregnancy has not been established. Breast feeding may be continued after administration of the product.

UNDESIRABLE EFFECTS Undesirable effects associated with Visipaque are usually mild to moderate and transient in nature. Serious reactions as well as fatalities are only seen on very rare occasions. Hypersensitivity reactions may present as respiratory or cutaneous symptoms like dyspnoea, rash, erythema, urticaria, pruritus, severe skin reactions, angioneurotic oedema, hypotension, fever, laryngeal oedema, bronchospasm or pulmonary oedema. They may appear either immediately after the injection or up to a few days later. Hypersensitivity reactions may occur irrespectively 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. Patients using beta blockers may present with atypical symptoms of hypersensitivity which may be misinterpreted as a vagal reaction. Neurological reactions, headache, dizziness, seizures, and transient motor or sensory disturbance (e.g. taste or smell alteration, transient blindness) may occur. Severe respiratory symptoms and signs (including dyspnoea and non-cardiogenic pulmonary oedema), and cough may occur. Also reported are; vagal reactions, cardiac arrhythmia, depressed cardiac function, ischaemia, hypertension and iodism. Arterial spasm may follow injection. A minor transient rise in creatinine is common. Renal failure is very rare. Post phlebographic phlebitis or thrombosis is very rare. Arthralgia is very rare. Intrathecal use: Headache, nausea, vomiting or dizziness. Mild local pain and pain at the site of injection may occur. Meningeal irritation giving photophobia and meningism and frank chemical meningitis have been observed with other non-ionic iodinated contrast media. The possibility of an infective meningitis should also be considered. Oral use: diarrhoea, nausea, vomiting, abdominal pain. Hysterosalpingography (HSG): Transient pain in the lower abdomen. Vaginal bleeding/discharge, nausea, vomiting, headache, fever. Arthrography: Pressure sensation and post procedural pain. In patients with autoimmune diseases cases of vasculitis and SJS-like syndrome were observed.

OVERDOSE is unlikely in patients with a normal renal function. The duration of the procedure is important for the renal tolerability of high doses of contrast media (t1/2 ~ 2 hours). 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.

PHARMACEUTICAL PARTICULARS

LIST OF EXCIPIENTS The following excipients are included: Trometamol, sodium chloride, calcium chloride, sodium calcium edetate, hydrochloric acid (pH adjustment) and water for injections. The pH of the product is 6.8 - 7.6.

SPECIAL PRECAUTIONS FOR STORAGE VISIPAQUE™ should be stored at up to 30°C protected from light. The product in polypropylene bottles may be stored at 37°C for up to 1 month prior to use.

INSTRUCTIONS FOR USE/HANDLING Like all parenteral products, VISIPAQUE should be inspected visually for particulate matter, discolouration and the integrity of the container prior to use. Not to be used if it is discoloured or contains a precipitate. The product should be drawn into the syringe immediately before use. Vials are intended for single use only, any unused portions must be discarded. VISIPAQUE may be warmed to body temperature (37°C) before administration.