PRESCRIBING INFORMATION SeHCAT 370 kBq Capsules ([^{75}Se]tauroselcholic acid)
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 Hard gelatin capsule containing [^{75}Se]tauroselcholic acid [370 kBq at the activity reference date].
INDICATIONS This medicinal product is for diagnostic use only. Used for the investigation of bile acid malabsorption and measurement of bile acid pool loss. It may be used in the assessment of ileal function, in the investigation of inflammatory bowel disease and chronic diarrhoea and in the study of entero-hepatic circulation.
DOSAGE AND METHOD OF ADMINISTRATION Normal adult and elderly dose is one capsule administered orally.
No paediatric dosage form or clinical experience of the use of this product in children. The same dose used in adults should be used in children. A careful assessment of the risk/benefit ratio should be undertaken before use of the product in children due to increased effective dose equivalent. Careful consideration of the activity to be administered to patients with hepatic impairment is required since increased radiation exposure is possible. Drinks of 15 ml of water are recommended before, during and after swallowing capsule to ensure passage to the stomach. Patient should be in standing or sitting position.
CONTRAINDICATIONS Hypersensitivity to the active substance or to any of the excipients.
WARNINGS AND PRECAUTIONS If hypersensitivity or anaphylactic reactions occur, administration must be discontinued immediately and if required, intravenous treatment initiated. The necessary medicinal products and equipment such as endotracheal tube and ventilator must be immediately available. Caution advised in administration of SeHCAT to patients with severe hepatic dysfunction or biliary tract obstruction as in these conditions, the radiation dose to the liver will be significantly increased. For each patient, the radiation exposure must be justifiable by the likely benefit.
The activity administered should be as low as reasonably achievable to obtain the required diagnostic information.
Careful consideration of the benefit risk ratio in patients with hepatic impairment is required since increased radiation exposure is possible. No data are available for the paediatric population however careful consideration of the indication is required since the effective dose per MBq is higher than in adults. This medicinal product contains 3.01 mmol (71.04 mg) sodium in each capsule which should be taken into account in patients on a low sodium diet.
INTERACTIONS No interaction studies have been performed to date. Bile acid sequestrants (BAS) such as cholestyramine and colesevelam, may interfere with SeHCAT results. It is recommended that BAS be discontinued for 7 days before the examination with SeHCAT and resumed after the 7th-day scan. Clinicians may need to consider symptomatic management, dietary modifications, or alternative therapies (and their combinations) based on relevant treatment guidelines and therapeutic protocols where appropriate during the 14-day period when patients are temporarily discontinuing BAS treatment.
PREGNANCY AND LACTATION When an administration of radiopharmaceuticals to a woman of childbearing potential is intended, it is important to determine whether or not she is pregnant. Any woman who has missed a period should be assumed to be pregnant until proven otherwise. If in doubt about the potential pregnancy, alternative techniques not using ionising radiation (if there are any) should be offered to the patient. No data are available on the use in human pregnancy. Animal reproduction studies have not been carried out. Radionuclide procedures carried out on pregnant women also involve radiation doses to the foetus. Only essential investigations should therefore be carried out when the likely benefit exceeds the risk to the mother and foetus. Before administration to a breastfeeding mother, consideration should be given as to whether the investigation could be reasonably delayed until after the mother has ceased breastfeeding and as to whether the most appropriate choice of radiopharmaceutical has been made, bearing in mind the secretion of activity in breast milk. If administration is considered necessary, breastfeeding should be interrupted and breast milk discarded for three to four hours after administration, after which breastfeeding can be resumed.
UNDESIRABLE EFFECTS Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. As the effective dose is 0.26 mSv when the maximal recommended activity of 370 kBq is administered these adverse reactions are expected to occur with a low probability. Immune system disorders: Hypersensitivity (unknown frequency).
DOSIMETRY Effective dose for a healthy adult administered one 370 kBq capsule of SeHCAT is typically 0.26mSv.
In most clinical investigations for which this substance is used (e.g. Crohn's disease) the effects of impaired ileal absorption and shorter gastrointestinal transit time tend to reduce the dose commitment compared with the normal case. However, in patients with severe cholestatic jaundice, the liver dose has been estimated to be about 100 times the normal value.
MARKETING AUTHORISATION HOLDER GE Healthcare Limited, Pollards Wood, Nightingales Lane, Chalfont St Giles, Buckinghamshire HP8 4SP, UK.
CLASSIFICATION FOR SUPPLY Subject to medical prescription (POM).
UK MARKETING AUTHORISATION NUMBER PL 00221/0105
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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.