SeHCAT, tauroselcholic acid
(Teksten er forkortet i forhold til det af Lægemiddelstyrelsen godkendte produktresumé, dette kan rekvireres vederlagsfrit fra GE Healthcare A/S).
Indehaver af markedsføringstilladelsen: *GE Healthcare Buchler, Braunschweig, Germany.* Dansk repræsentant: *GE Healthcare A/S, Herlev.*

ACTIVE INGREDIENTS Tauroselcholic (^{75}Se) acid 370 kBq at the activity reference date.

INDICATIONS For diagnostic use only. Tauroselcholic (^{75}Se) acid is 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.

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

ADVERSE REACTIONS AND RISKS
Special warnings and precautions before use: The possibility of hypersensitivity should always be considered. Advanced life support facilities should be readily available. Caution is advised in the administration of tauroselcholic (^{75}Se) acid to patients with severe hepatic dysfunction or biliary tract obstruction as in these conditions radiation dose to the liver will be significantly increased. For each patient, exposure to ionising radiation must be justifiable on the basis of likely benefit. The activity administered must be such that the resulting radiation dose is as low as reasonably achievable bearing in mind the need to obtain the intended diagnostic or therapeutic result. Excipients: This medicinal product contains 3.01 mmol (71.04 mg) sodium in each capsule. To be taken into consideration for patients on a controlled sodium diet.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS FOR INTERACTION No interaction studies have been performed to date. *Bile acid sequestrants (BAS)* such as cholestyramine and colesevelam, may interfere with SeHCAT results, since BAS may form insoluble complexes with SeHCAT which are excreted via faeces. There is no clinical data investigating this interaction. However, it is recommended that BAS be discontinued for 7 days before the examination with SeHCAT and resumed after the 7th-day scan. *Pancreatin* Treatment with pancreatin may impact bile salt absorption in EPI (exocrine pancreatic insufficiency) patients having a potential effect in the gastro-intestinal transit. There is no clinical data investigating this interaction. However, this effect should be considered when interpreting SeHCAT scan results. It is advised that pancreatin is discontinued at the last meal before the examination with SeHCAT and resumed after the 7th-day scan.

FERTILITY, PREGNANCY AND LACTATION SeHCAT should only be administered during pregnancy when the likely benefit exceeds the risk incurred by the mother and the foetus. Before administering a radioactive medicinal product to a mother who is breast feeding consideration should be given as to whether the investigation could be reasonably delayed until after the mother has ceased breast feeding and as to whether the most appropriate choice of radiopharmaceutical has been made, bearing in mind the secretion of activity in breast milk. If the administration is considered necessary, breast feeding should be interrupted for 3 to 4 hours after tauroselcholic (75Se) acid administration and the expressed feeds discarded.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES None.

ADVERSE REACTIONS Adverse reactions to tauroselcholic (^{75}Se) acid are rare. A few instances of possible allergic reactions have been reported following tauroselcholic (^{75}Se) acid administration, but causality has not been firmly established. Exposure to ionizing 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. Undesirable effects: not known (cannot be estimated from the available data): Hypersensitivity. *Overdose:* It is considered that overdosage is unlikely as the product is presented as a capsule which is administered orally in a controlled clinical setting. Should overdosage occur there are no known procedures which could be used to increase the clearance of activity from the body.

DOSAGE *Adults:* The normal dose for adults and the elderly is one capsule, administered orally. *Children:* If the product is to be administered to children the same dosage as in adults is used. There is no paediatric dosage form or clinical experience of the use of this product in children. A careful assessment of the risk/benefit ratio should be undertaken before use of this product in children, particularly since the use of a fixed dose result in an increased effective dose equivalent in children. To ensure smooth passage of the capsule into the stomach, it is recommended that 15 ml drinks of water are taken by the patient before, during and after swallowing the capsule. The patient should be in a sitting or standing position during administration.

PHARMACEUTICAL FORM Capsules

PACK SIZE Single capsule packs.

UDLEVERINGSGRUPPE -. **TILSKUDSSTATUS** Ikke tilskudsberettiget.

Date of revision of text: March 2026 – based on SmPC dated December 2025.