SUMMARY OF PRODUCT CHARACTERISTICS

for

SeHCAT, capsule

1. NAME OF THE MEDICINAL PRODUCT

SeHCAT

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Tauroselcholic (^{75}Se) acid is supplied as capsules of 370 kBq at the activity reference date.

Each capsule contains less than 0.1mg of tauroselcholic acid.

Selenium-75 has a physical half-life of approximately 118 days and decays by gamma emission with principal energies at 0.136 MeV and 0.265 MeV.

Excipient(s) with known effect
Sodium: 71.04 mg/capsule

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsule.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

This medicinal product is 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.

4.2 Posology and method of administration

Posology
Adults and elderly patients
The normal dose for adults and the elderly is one capsule, administered orally.

Paediatric population
If the product is to be administered to children the same dosage as in adults is used (see section 4.4 and 11).
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 (see section 11).

Hepatic impairment
Careful consideration of the activity to be administered is required since an increased radiation exposure is possible in these patients.

Method of administration
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.

The instructions for preparation of radiopharmaceuticals are given in section 12.

For patient preparation, see section 4.4.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Potential for hypersensitivity or anaphylactic reactions
If hypersensitivity or anaphylactic reactions occur, the administration of the medicinal product must be discontinued immediately and intravenous treatment initiated, if necessary. To enable immediate action in emergencies, the necessary medicinal products and equipment such as endotracheal tube and ventilator must be immediately 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.

Individual benefit/risk justification
For each patient, the radiation exposure must be justifiable by the likely benefit. The activity administered should in every case be as low as reasonably achievable to obtain the required diagnostic information.

Hepatic impairment
Careful consideration of the benefit risk ratio in these patients is required since an increased radiation exposure is possible.

Paediatric population
No data are available. Careful consideration of the indication is required since the effective dose per MBq is higher than in adults (see section 11).

Patient preparation

The patient should be well hydrated before the start of the examination and urged to void as often as possible during the first hours after the examination in order to reduce radiation.

Specific warnings
This medicinal product contains 3.01 mmol (71.04 mg) sodium in each capsule. This should be taken into account in patients on a low sodium diet.

Precautions with respect to environmental hazard see section 6.6.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed and no interactions have been reported to date.

4.6 Fertility, pregnancy and lactation

Women of childbearing potential
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 (if the woman has missed a period, if the period is very irregular, etc.), alternative techniques not using ionising radiation (if there are any) should be offered to the patient.

Pregnancy
No data are available on the use of this product in human pregnancy. Animal reproduction studies have not been performed.

Radionuclide procedures carried out on pregnant women also involve radiation doses to the foetus. Only essential investigations should therefore be carried out during pregnancy, when the likely benefit far exceeds the risk incurred by the mother and the foetus.

Breast-feeding
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. Breast milk should be expressed and discarded about three to four hours after tauroselcholic (^{75}Se) acid administration, after which breast feeding can be resumed.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable effects

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 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.

The frequencies of undesirable effects are defined as follows:
Very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000) and not known (cannot be estimated from the available data)

Immune system disorders
Not known: Hypersensitivity

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system:

Norway
Statens legemiddelverk
Nettside: www.legemiddelverket.no/meldeskjema

Paediatric population
No data are available.

4.9 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.

Paediatric population
No data are available.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other hepatic and reticulo endothelial system diagnostic radiopharmaceuticals
ATC Code: V09D X01

Mechanism of action
Tauroselcholic acid is a bile acid analogue which shows identical physiological behaviour with naturally occurring bile acid conjugates.

Pharmacodynamic effects

At the chemical concentrations and activities used for diagnostic procedures tauroselcholic (^{75}Se) acid does not appear to exert any pharmacodynamic effects.

Clinical efficacy and safety
See Pharmacodynamic effects.

Paediatric population
No data are available.

5.2 Pharmacokinetic properties

Distribution:
The distribution of activity is almost entirely confined to the lumen of the biliary ducts, gut and liver.

Organ uptake
Following oral administration in normal subjects, approximately 95% of the labelled bile acid is absorbed, mainly by the terminal ileum during each enterohepatic cycle.

Elimination
See Half-life

Half-life
Whole body retention data from normal subjects showed 97 to 100% of tauroselcholic (^{75}Se) acid was excreted with a biological half-life of 2.6 days and that, in most cases, a small component of about 3% was eliminated with a mean half time of 62 days.

Paediatric population
No data are available.

5.3 Preclinical safety data

A single dose study in rats has indicated a safety margin of greater than 10,000 times the maximum human oral dosage. This agent is not intended for regular or continuous administration. Repeat dose toxicity studies, mutagenicity and long-term carcinogenicity studies have not been performed.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium phosphate dihydrate
Gelatin capsule

The gelatin capsule contains the following ingredients:
Titanium dioxide
Quinoline yellow
Erythrosine
Gelatin

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

18 weeks from the date of manufacture. The activity reference date is 12 weeks before expiry.

6.4 Special precautions for storage

Store below 25°C. Do not freeze. Protect from light

Store in accordance with national regulations for radioactive materials.

6.5 Nature and contents of container

SeHCAT is available in polystyrene containers with polythene caps. The capsules are held in place with polythene foam pads.

Pack size: single capsule packs.

6.6 Special precautions for disposal and other handling

General warning

Radiopharmaceuticals should be received, used and administered only by authorized persons in designated clinical settings. Their receipt, storage, use, transfer and disposal are subject to the regulations and/or appropriate licenses of the competent official organization.

Radiopharmaceuticals should be prepared in a manner which satisfies both radiation safety and pharmaceutical quality requirements. Appropriate aseptic precautions should be taken.

If at any time in the preparation of this product the integrity of this container is compromised it should not be used.

Administration procedures should be carried out in a way to minimize risk of contamination of the medicinal product and irradiation of the operators. Adequate shielding is mandatory.

The administration of radiopharmaceuticals creates risks for other persons from external radiation or contamination from spill of urine, vomiting, etc. Radiation protection precautions in accordance with national regulations must therefore be taken.

Any unused product or waste material should be disposed of in accordance with local requirements for radioactive material.

7. MARKETING AUTHORISATION HOLDER

GE Healthcare Buchler GmbH & Co. KG
Gieselweg 1
38110 Braunschweig
Germany

8. MARKETING AUTHORISATION NUMBER

MTnr: 8321

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 07.01.1999
Date of last renewal: 30.01.2010

10. DATE OF REVISION OF THE TEXT

08.01.2019

11. DOSIMETRY

The table below shows the dosimetry as calculated according to the publication 80 of the ICRP (International Commission of Radiological Protection, Radiation Dose to Patients from Radiopharmaceuticals, Pergamon Press, 1998).

Absorbed dose per unit activity administered(mGy/MBq)

Organ	Adult	15 years	10 years	5 years	1 year
Adrenals	3.2E-01	4.lE-01	6.2E-01	9.4E-01	1.5E+00
Bladder	3.3E-01	4.2E-01	6.7E-0l	l.0E+00	l.7E+00
Bone surfaces	2.3E-01	3.0E-0l	4.3E-0l	6.4E-01	l.2E+00
Brain	4.8E-02	5.6E-02	7.9E-02	1.2E-01	2.0E-01
Breast	7.7E-02	9.6E-02	1.8E-01	2.8E-01	5.2E-01
Gall bladder	6.4E+00	7.lE+00	9.0E+00	l.5E+0l	4.8E+0l
GI-tract					
Stomach	4.2E-0l	5.5E-0l	9.3E-0l	l.5E+00	2.5E+00
SI	l.9E+00	2.4E+00	3.8E+00	5.9E+00	l.0E+0l
Colon	2.0E+00	2.4E+00	3.8E+00	5.8E+00	l.0E+0l
(ULI	l.9E+00	2.3E+00	3.5E+00	5.3E+00	9.lE+00)
(LLI	2.lE+00	2.6E+00	4.2E-00	6.5E+00	l.2E+0l)
Heart	3.3E-0l	4.3E-0l	6.4E-0l	9.6E-0l	l.6E+00
Kidneys	5.0E-0l	6.lE-0l	8.9E-0l	l.3E+00	2.0E+00
Liver	6.9E-0l	8.7E-0l	l.3E-00	l.8E-00	3.2E+00
Lungs	2.4E-0l	3.3E-0l	4.7E-0l	7.2E-0l	l.3E+00
Muscles	2.0E-0l	2.5E-0l	3.7E-0l	5.5E-0l	9.8E-0l
Qesophagus	l.lE-0l	l.4E-0l	l.9E-0l	2.9E-0l	4.8E-0l
Ovaries	l.0E+00	l.3E+00	2.0E+00	2.9E+00	4.9E+00
Pancreas	4.5E-0l	5.8E-0l	l.lE+00	l.7E+00	2.6E+00
Red marrow	2.9E-0l	3.4E-0l	4.6E-0l	6.0E-0l	8.3E-0l
Skin	7.5E-02	9.lE-02	l.4E-0l	2.2E-0l	4.2E-0l
Spleen	3.0E-0l	4.lE-0l	6.6E-0l	l.0E+00	l.7E+00
Testes	9.2E-02	1.3E-0l	2.2E-0l	3.7E-0l	7.0E-0l
Thymus	l.lE-01	l.4E-0l	1.9E-0l	2.9E-0l	4.8E-0l
Thyroid	6.9E-02	9.6E-02	l.5E-0l	2.7E-0l	5.2E-0l
Uterus	7.5E-0l	9.4E-0l	l.5E+00	2.3E+00	3.8E+00
Remaining organs	2.6E-0l	3.4E-0l	5.3E-0l	8.3E-0l	1.3E+00
Effective dose (mSv/MBq)	**6.9E-01**	**8.6E-01**	**1.3E+00**	**2.0E+00**	**3.9E+00**

For this product the effective dose to a healthy adult resulting from the administration of a 370kBq capsule 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.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.