

PACKAGE LEAFLET: INFORMATION FOR THE USER

SeHCAT 370 kBq capsules

[⁷⁵Se]tauroselcholic acid

(called SeHCAT in this leaflet)

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your nuclear medicine doctor who will supervise the procedure.
- If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What SeHCAT is and what it is used for
2. What you need to know before SeHCAT is used
3. How SeHCAT is used
4. Possible side effects
5. How SeHCAT is stored
6. Contents of the pack and other information

1. What SeHCAT is and what it is used for

This medicine is a radiopharmaceutical product for diagnostic use only. It is used only to help identify illness of certain sections of the digestive system.

SeHCAT is given before a scan and helps a special camera see inside a part of your body.

- It contains an active ingredient called ‘tauroselcholic acid’.
- Once swallowed it can be seen from outside your body by a special camera used in the scan.
- The scan can help your doctor see how well your digestive system is working.

Your doctor or nurse will explain which part of your body will be scanned.

The use of SeHCAT does involve exposure to small amounts of radioactivity. Your doctor and the nuclear medicine doctor have considered that the clinical benefit that you will obtain from the procedure with the radiopharmaceutical outweighs the risk due to radiation.

2. What you need to know before SeHCAT is used

SeHCAT must not be used:

- If you are allergic (hypersensitive) to the active ingredient or any other ingredients (listed in Section 6).

Warnings and precautions

Please talk to your nuclear medicine doctor who is conducting the investigation before you are given SeHCAT.

Take special care with SeHCAT

Talk to your doctor or nurse before having SeHCAT:

- If you have been told by a doctor that your liver is not working properly or that there is a blockage in your bile ducts.

- If you are pregnant or believe you might be pregnant.
- If you are breast-feeding.
- This medicinal product contains 3.01 mmol (or 71.04 mg) sodium per capsule. To be taken into consideration by patients on a controlled sodium diet.

Children and adolescents

Talk to your nuclear medicine doctor if you are under 18 years old.

Other medicines and SeHCAT

Please tell your nuclear medicine doctor if you are taking, have recently taken or might take any other medicines, as some medicines may interfere with SeHCAT scan result.

Your doctor may recommend that you stop taking the following medicines before the administration of SeHCAT as these medicines may interfere with the SeHCAT image interpretation:

Medicines like Bile Acid Sequestrants (BAS) such as Cholestyramine and Colesevelam, commonly used in the treatment of hypercholesterolemia, may interfere with the test results, since BAS may form insoluble complexes with SeHCAT which are excreted via faeces. It is recommended to stop taking medicines such as Cholestyramine and Colesevelam 7 days before the examination with SeHCAT and treatment can be resumed after the 7th-day scan.

Pancreatin contains pancreatic enzymes necessary for digestion, that is to help break down fats, starches, and proteins. Treatment with pancreatin may impact bile salt absorption in EPI (exocrine pancreatic insufficiency) patients having a potential effect in the gastro-intestinal transit. It is advised that pancreatin is discontinued at the last meal before examination with SeHCAT and resumed after the 7th-day scan.

If you are unsure that any of the above applies to you, tell your nuclear medicine doctor or nurse before having SeHCAT.

Having SeHCAT with food and drink

- You may be asked to take drinks of water before, during and after swallowing the capsule.

Pregnancy, breast-feeding, and fertility

You must inform the nuclear medicine doctor before the administration of SeHCAT if there is a possibility you might be pregnant, if you have missed your period or if you are breast-feeding.

When in doubt, it is important to consult your nuclear medicine doctor who will supervise the procedure.

If you are pregnant

If you are pregnant or think you may be pregnant, tell your doctor. Your doctor will only use this product if it is considered that the benefit outweighs the risk.

If you are breast-feeding

Do not breast-feed if you are given SeHCAT. This is because small amounts of 'radioactivity' may pass into the mother's milk. If you are breast-feeding, your doctor may wait until you have finished breast-feeding before using SeHCAT. If it is not possible to wait your doctor will ask you to:

- stop breast-feeding for 3 to 4 hours, and
- use formula feed for your child, and
- express (remove) breast milk and throw away the milk.

Your doctor will let you know when you can start breast-feeding again.

Driving and using machines

Ask your doctor if you can drive or use machines after you have been given SeHCAT.

3. How SeHCAT is used

There are strict laws on the use, handling and disposal of radiopharmaceutical products. SeHCAT will only be used in special controlled areas. This product will only be handled and given to you by people who are trained and qualified to use it safely. These persons will take special care for the safe use of this product and will keep you informed of their actions.

The nuclear medicine doctor supervising the procedure will decide on the quantity of SeHCAT to be used in your case. It will be the smallest quantity necessary to get the desired information.

The quantity to be administered usually recommended for an adult is one capsule and the maximal recommended activity is 370 kBq (kilobecquerel, the unit used to express radioactivity).

Administration of SeHCAT and conduct of the procedure

SeHCAT is administered by oral administration.

One capsule is sufficient to conduct the test that your doctor needs.

You should be sitting or standing when you take the capsule.

Duration of the procedure

Your nuclear medicine doctor will inform you about the usual duration of the procedure.

The nuclear medicine doctor will inform you if you need to take any special precautions after receiving this medicine. Contact your nuclear medicine doctor if you have any questions.

Use in children and adolescents

If the product is to be administered to children the same dosage as in adults is used.

If you have been given more SeHCAT than you should

An overdose is unlikely because you will only receive a single dose of SeHCAT precisely controlled by the nuclear medicine doctor supervising the procedure. However, in the case of overdose, you will receive the appropriate treatment.

Should you have any further questions on the use of SeHCAT, please ask the nuclear medicine doctor who supervises the procedure.

4. Possible side effects

Like all medicines, SeHCAT can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Allergic reactions (frequency not known)

If you have an allergic reaction when you are in hospital or a clinic having the scan, tell the doctor or nurse straight away. The signs may include:

- skin rash or itching or flushing
- swelling of the face
- difficulty in breathing

If any of these side effects above happen after you leave the hospital or clinic, go straight to the casualty department of your nearest hospital.

This radiopharmaceutical will deliver low amounts of ionising radiation associated with the least risk of cancer and hereditary abnormalities (passing on faulty genes).

Reporting of side effects

If you get any side effects, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse. You can also report side effects directly via the national reporting system:

HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
E-mail: medsafety@hpra.ie

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How SeHCAT is stored

You will not have to store this medicine. This medicine is stored under the responsibility of the specialist in appropriate premises. Storage of radiopharmaceuticals will be in accordance with national regulations on radioactive materials.

The following information is intended for the specialist only.

SeHCAT is kept out of the sight and reach of children.

Do not use this medicine after the expiry date and time, which are stated on the label after 'EXP'.

6. Contents of the pack and other information

What SeHCAT contains

- The active ingredient is [⁷⁵Se]tauroselcholic acid. Each capsule of SeHCAT contains 370 kBq (kilobecquerel – the unit in which radioactivity is measured) of [⁷⁵Se]tauroselcholic acid.
- The other ingredients are disodium phosphate dihydrate and a capsule (containing titanium dioxide, quinoline yellow, erythrosine and gelatin).

What SeHCAT looks like and contents of the pack

SeHCAT is a hard capsule supplied in a polystyrene container.

One capsule contains 370 kBq (kilobecquerels, the unit used to express radioactivity).

Marketing Authorisation Holder

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D-38110 Braunschweig
Germany

Manufacturer

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Marketing Authorisations

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