75Se tauroselcholic acid

SeHCAT

1. Indications

⁷⁵Se-tauroselcholic 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 diarrhea and in the study of entero-hepatic circulation.

2. Preparation

Approved product, supplied as capsules of 370 kBq at the activity reference date

3. Quality control

Approved product, see summary of product characteristics (SmPC) and the European Pharmacopeia.

4. Interactions

Cholestyramine medication should be discontinued at least three days before the investigation.

No interaction studies have been performed.

5. Adverse reactions

Hypersensitivity reactions have been reported.

6. Biodistribution & pharmacokinetics

Tauroselcholic acid is a bile acid analogue which shows identical physiological behaviour with naturally occurring bile acid conjugates. Following oral administration in normal subjects, approximately 95% of the labelled bile acid is absorbed, mainly by the terminal ileum during each enterohepatic cycle. The distribution of activity is almost entirely confined to the lumen of the biliary ducts, gut and liver. Whole body retention data from normal subjects showed 97-100% of 75Se-tauroselcholic 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.

7. Stability

The shelf life for this product is 18 weeks from the date of manufacture. The activity reference date is 12 weeks before expiry.

8. Literature

SmPC SeHCAT 370 kBg capsules.