^{14}C urea

HeliCap®

1. Indications

For *in-vivo* diagnosis of *Helicobacter pylori* infection in the gastrointestinal tract (stomach and duodenum).

2. Preparation

Approved product supplied as capsules of 37 kBq at the activity reference date. Alternatively, ^{14}C-urea can be administered as a liquid test dose of 200 kBq ^{14}C and 350 mg urea in water.

3. Quality control

Approved product, see summary of product characteristics (SmPC).

4. Interactions

The urea breath test will be affected by all treatments interfering with *Helicobacter pylori* such as antibiotics, bismuth salts, or acid inhibitors.

Suppression of *Helicobacter pylori* may lead to false negative results. After treatment with antibiotics or bismuth salts one month should pass before the test is performed. After treatment with acid inhibitors at least one week should pass. This is especially important after eradication therapy.

5. Adverse reactions

No adverse reactions have been reported.

6. Biodistribution & pharmacokinetics

After ingestion of a ^{14}C urea capsule, it rapidly disintegrates in the stomach and the ^{14}C labeled urea reaches the gastric mucosa. If *Helicobacter pylori* is present, the (^{14}C) urea is metabolized to carbon dioxide and ammonia by the urease enzyme in the *Helicobacter pylori*.

$$H_2N(^{14}CO)NH_2 + H_2O \xrightarrow{Urease\ Enzyme} 2NH_3 + {}^{14}CO_2$$

The orally applied (^{14}C) urea is metabolized to carbon dioxide and ammonia or is integrated into the body's own urea cycle. Absorption and distribution of the $^{14}CO_2$ occurs faster than the urease reaction. The limiting step in the process is thereby the ability of the urease to metabolize (^{14}C) urea.

7. Stability

The shelf-life of the product is 2 years after the date of release. Store below 25°C.

8. Literature

- SmPC HeliCap, 37 kBq, capsule, hard.
- Balon HR et al. Society of Nuclear Medicine Procedure Guideline for C-14 urea breath test, version 3, approved June 23, 2001.