

Approval Date: July 31th,2017
Modification Date: March 15th, 2021

Urea-[¹³C] Tablets Breath Test Kit Package Insert

Please read through this package insert carefully and use the product under the guidance of your doctor.

[Test Kit Name]

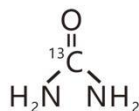
Generic Name: Urea-[¹³C] Capsule Breath Test Kit

[Composition]

Main composition: Urea-[¹³C]

Structural Formula:

Molecular formula: (NH₂)₂¹³CO
Molecular weight 61.06



[Character]

Yellow or white tablets

[Indication]

Urea-[¹³C] tablets Breath Test Kit is intended for use in the diagnosis of Helicobacter Pylori(H. Pylori) infection in human stomach.

[strength]

Each Urea-¹³C tablets contains 45mg Urea-[¹³C].

[Usage and Dosage]

1. The test should be conducted on an empty stomach or at least two

hours after eating.

2. Fill in the labels on the breath collection tubes/breath bag.

3. Collect baseline breath sample:

3.1 For test kit with breath collection tubes, insert one plastic blowing pipe into the bottom of baseline breath collection tube and blow repositively into the collection tube through the blowing for 5 seconds.

Take out the blowing pipe slowly during blowing and fasten down the collection tube cap as soon as the tube is filled up.

3.2 For test kit with breath bags, remove the cap from the baseline breath bag and blow into the bag through the mouthpiece, and then screw up the cap when the bag is filled up.

4. Take one urea-[¹³C] tablets with 80-100ml water and then sit calmly for 20 minutes.

5. Repeat the same blowing step to collect post-dose breath sample

And fasten down the breath collection tube/breath bag.

6. Test the baseline and pose-dose breath sample with Breath Test

Analyzer. If there is any leakage with the breath bag, please

Re-collect the patient's breath.

7. DOB value(%) is used for judging Helicobacter pylori infection:

$$DOB(\%) = \frac{\text{Abundance of } ^{13}\text{C in pose - dose sample} - \text{Abundance of } ^{13}\text{C in baseline}}{\text{Natural abundance of } ^{13}\text{C}} \times 1000$$

8. Judgment

DOB(≥)4.0: positive

[Adverse reaction]

No observed adverse reaction.

[Contraindications]

Hypersensitivity to the active substance or any of the excipients.

[Precautions]

1. The patient should have an empty stomach or fast for at least two hours. Factors list below may affect the diagnosis from the text:

(1) The patient took Helicobacter pylori sensitive drugs such a

antibiotics, bismuth preparations and proton pump inhibitors within one month.

(2) It should be noted that Helicobacter pylori can be restrained during hemorrhage time of upper alimentary

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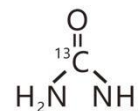
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(2) It should be noted that Helicobacter pylori can be restrained during hemorrhage time of upper alimentary

cannal, and thus It makes the test false negative. If the hemorrhage of alimentary canal was over for more than one week, the diagnosis won't be affected.

(3) Partial gastrectomy may allow the isotope to be discharged from the stomach quickly or make the patient lack the stomach acid.

2. Be sure to fasten down the cap of breath collection tube/breath bag immediately after blowing.
3. Be sure to insert the plastic blowing pipe into the bottom of the breath collection tube.

[Use for pregnant and lactating woman]

Applicable

[Use for children]

Applicable

[Test Kit overdose]

No known interaction. Taking antibiotics within one month or proton pump inhibitors within one week may give false results.

[Test Kit overdose]

The Urea contained in the kit is approximately 0.15% of the amount produced by human body each day. No concern for overdose.

[Pharmacology and toxicology]

As urease doesn't exist in the cells of mammals, besides, no other bacteria are found in the stomach, the urease in human's stomach proves the existence of helicobacter pylori.

Once the patient take Urea-¹³C orally, if helicobacter pylori exist, the urease produced by helicobacter pylori in the stomach will quickly decompose the urea into ¹³CO₂ and ammonia, and ¹³CO₂ will go into the lung via the blood and be discharged out of the body. Therefore, it can be judged whether the patient is infected by helicobacter pylori measuring the variation of 13C/12C isotopic ration in the patient's breath.

[Pharmacokinetics]

Orally taken Urea-¹³C can be quickly absorbed to reach the peak value of absorption within 0.11 hours. It can also be discharged quickly with half life as 5.15 hours, kidney clearance rate as 0.617L.KG⁻¹.h⁻¹.The Test Kit can be excreted soon mainly in the form of urine. 65% of it can be discharged through urine and excrement within 24 hours. The result of tests on animal shows that no isomerism accumulation is seen in animal's tissues such as heart, liver, lung, kidney, muscle, brain, fat. The biologic half life during which the urea is discharged form other parts of the body to the bladder is 6 hours.

[Storage]

Sealed up and stored in cool and dry condition(under 20°C)

[Package]

One Urea-[13C] tablets in Aluminum Foil Package and two breath bags.

[Validity]

24 months.

[Executed standard]

YBH05352017

[Registered number of approval]

H20174047

[Manufacturer]

Name: Beijing Haiderun Pharmagroup Co., Ltd.
Add : 16# Guangyuan Road, Tongzhou industrial Park, Beijing China
P. C.:101113
Tel:+86-010-61569805
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