



Headway Urea 14C Capsules

[Drug name]

Generic Name: Urea 14C Capsules

[Ingredients]

The major ingredient of this product is Urea 14C.

[Half-time of radioactive nuclide] Half-time of ^{14}C : 5730 years

[Radioactivity and indicated time]

Radioactive activity: 2.78×10^{-2} MBq (0.75×10^{-3} mCi). Indicated time: Same as Date of Manufacture.

[Indication]

For the diagnosis of *Helicobacter Pylori* (HP) infection.

[Administration and Dosage]

1. This product should be used together with the breath collecting reagent of the Urea 14C Breath Test Kit or the processed materials of breath test analyzer.
2. The test should be conducted on an empty stomach or at least two hours after eating. The patient should gargle before the test.
3. The patient takes one Urea 14C capsule with 20mL of cool water, and then sits calmly for 15~25 minutes.
4. Follow the instructions of package insert or user's manual for medical device to collect the patient's breath.
5. Mark on the breath sample after it is collected.
6. Test the breath sample on approved breath test analyzer for Urea 14C Breath Test.

[Overdosage]

In the event of overdose, the patient should drink one glass of water (150mL) every hour to hasten excretion of the radioisotope. Maximum excretion of urea achieved at a urine output of $> 2.0\text{mL/min}$.

[Adverse reaction(s)]

There were no adverse reactions reported in clinical trials at a rate $>1\%$. All adverse reactions reported were felt by the investigators to be unrelated to the drug.

[Contraindications] Unknown.

[Precautions]

1. Pregnant and lactation women should not take such test.
2. The capsule should be taken orally without chewing.
3. Factors list below may affect the diagnosis from the test:

Factor	Result	Comment
Recent antibiotic or bismuth containing products	False neg.	Relapse of partially treated <i>Helicobacter pylori</i> (Hp) may take 1-4 weeks
Omeprazole (or other proton pump inhibitors)	False neg.	These agents suppress Hp in 40% of patients. Discontinue for at least 1 week before performing the PY test.
Sucralfate	False neg.	These agents suppress Hp
Resective gastric surgery	False neg.	Isotope may empty rapidly from the stomach
Resective gastric surgery	False pos.	Patient may be achlorhydric and have bacterial overgrowth (non-Hp urease)
Food in stomach (also bezoar, gastroparesis)	Unknown	Isotope may not come into contact with gastric mucosa. Patient may be achlorhydric and/or have overgrowth (non-Hp urease).

4. Do not take a broken capsule.

[Precautions General]

After the patient ingest the Urea 14C capsule, the sample collected for test purposes is for in vitro diagnostic use only. A false positive test could occur in patients who have achlorhydria. Very rarely, a false positive test may occur due to urease associated with *Helicobacters* other than *H.pylori* (e.g. *Helicobacter heilmannii*). Limitations to the Test

- The test has been evaluated in outpatients before elective endoscopy
- Test result should be considered together with clinical signs and patient history when diagnosing *H.pylori* infection
- A negative Results does not completely rule out the possibility of *H. Pylori* infection. If clinical sign and patient history suggest *H.Pylori* infection, repeat the test or use an alternative method.

[Information for Patients]

It is necessary for the patient to fast for 6 hours before the test.

The patients should not have taken antibiotics or bismuth containing products for 1 month, sucralfate for 2 weeks and proton pump inhibitors for 1 week prior to the test. Instruct the patient not to handle the capsule directly as this may interfere with the test result. The capsule should be swallowed intact. The capsule should not be chewed.

[Carcinogenesis, mutagenesis, impairment of fertility]

No studies have been conducted with Urea 14C to evaluate its potential for carcinogenicity, impairment of fertility, or mutagenicity.

[Drug Interaction]

Antibiotics, proton pump inhibitors, sucralfate, and bismuth containing drug preparations are known to suppress *H.pylori*. Ingestion of antibiotics or



bismuth within 4 weeks, sucralfate within 2 weeks or proton pump inhibitors within 1 week prior to performing the test may give false negative results.

[Pregnancy]

Animal reproduction studies have not been conducted with Urea 14C. It is also not known whether Urea 14C can cause foetal harm when administered to a pregnant woman or can affect reproduction capacity. When administration of Urea 14C to a woman of child bearing potential is considered, information should always be sought about pregnancy.

[Nursing mothers]

It is not known whether this drug is excreted in human milk

[Pediatric Use]

Clinical studies in children have not been conducted

[Post treatment Evaluation]

A negative Urea 14C 28 days after completing antibiotic treatment is evidence that the infection has been eradicated.

[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 takes Urea 14C orally, if helicobacter pylori exist, the urease produced by Helicobacter pylori in the stomach will quickly decompose the Urea into $^{14}\text{CO}_2$ and ammonia, and $^{14}\text{CO}_2$ 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 by measuring the $^{14}\text{CO}_2$ from patient's breath.

[Pharmacokinetics]

The Urea 14C administered orally can be quickly absorbed, and the peak blood concentration can be reached at 0.11 hour. Its elimination is relatively quick, with the half-life of elimination being 5.15 hour and the kidney clearance rate being $0.617 \text{ L.Kg}^{-1}.\text{h}^{-1}$. The excretion is very quick mainly through urine, and 65% will be excreted from the urine and stool within 24 hours. No specific accumulation was noted in the 12 kinds of tissues including heart, liver, lung, kidney, muscle, stomach, intestine, bone, brain, fat, genital glands in animal experiments. The biologic half-life of urea eliminated from other parts in the body to the urinary bladder is 6 hours.

[Clinical study]

In one of clinical study published report, the result was shown that diagnostic by 14C Urea have sensitivity 100%, Specificity 80% and accuracy 93%.

Another study to prove sensitivity, specificity and accuracy of 14C 0.75 μC Urea was carried out by comparing the results of the breath test with histological examination + urease output which is the standard in *H.pylori* examination. The results were shown that sensitivity 96.5%, specificity 91.8% and accuracy of 94.6%.

HARUS DENGAN RESEP DOKTER

[Storage]

Store below 30°C, keep tightly sealed.

[Package]

Box, 2 Aluminium pouch @ 2 blister @ 10 Capsules.

[Expiry date]

24 months.

[Nomor Izin Edar]

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[Imported by]

PT. Kaliroto

Sidorame 19 - Surabaya , Jawa Timur

[Manufactured by]

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INFORMASI PRODUK UNTUK PASIEN

- | | |
|---|---|
| 1. Nama obat | HEADWAY |
| 2. Bentuk sediaan | Kapsul |
| 3. Pemerian Obat | Serbuk putih di dinding bagian dalam kapsul berwarna orange dan kuning |
| 4. Apa yang terkandung dalam obat | Urea 14C dengan kekuatan 27.8 Kbpq (0.75 µCi) |
| 5. Untuk apa obat digunakan ? | Untuk diagnosis infeksi Helicobacter Pylori (HP) |
| 6. Bagaimana cara pemberian obat ? | <p>Satu kapsul langsung ditelan bersama dengan air sebagai satu administrasi pada saat pengujian.</p> <p>Sebelum minum obat, pasien harus berpuasa setidaknya 2 jam, lebih baik semalam.</p> <p>Ambil dosis normal dan lakukan tes ulang.</p> |
| 7. Bagaimana cara menggunakan obat ? | <p>Pasien harus berpuasa selama 6 jam sebelum tes. Anda tidak boleh menggunakan antibiotik atau obat yang mengandung Bismut selama satu bulan, Sukralfat selama 2 minggu dan penghambat pompa proton selama 1 minggu sebelum pengujian.</p> <p>Instruksikan pasien untuk tidak memegang kapsul secara langsung karena ini dapat mengganggu hasil tes.</p> |
| 8. Kapsul harus ditelan utuh. | Kapsul sebaiknya tidak dikunyah. |
| 9. Beritahukan kepada dokter Anda sebelum menggunakan obat ini jika : | Anda sedang hamil dan menyusui. |
| 10. Apa yang perlu diperhatikan bila menggunakan obat ini ? | <p>a. Wanita hamil dan menyusui sebaiknya tidak mengikuti test tersebut.</p> <p>b. Kapsul harus ditelan tanpa mengunyah.</p> <p>c. Daftar faktor di bawah ini dapat mempengaruhi diagnosis dari tes :</p> <ul style="list-style-type: none">• Anda sedang meminum obat sensitif Helicobacter Pylori seperti antibiotik, bismuth dan obat asam lambung golongan penghambat pompa proton di dalam satu bulan terakhir.• Perlu dicatat bahwa Helicobacter Pylori dapat ditahan selama waktu pendarahan saluran pencernaan bagian atas, dan dengan demikian dapat membuat hasil tes negatif palsu. Jika pendarahan saluran pencernaan sudah berakhir lebih dari satu minggu, diagnosis tidak akan terpengaruh.• Gastrektomi parsial memungkinkan isotop dikeluarkan dari perut cepat atau membuat pasien kekurangan asam lambung. |

INFORMASI PRODUK UNTUK PASIEN

- Jangan minum kapsul yang rusak
11. Obat dan makanan apa yang harus dihindari jika menggunakan obat ini ? Antibiotik, obat asam lambung golongan penghambat pompa proton, sukralfat dan sediaan obat yang mengandung bismuth dalam 1 minggu sebelum melakukan tes dapat memberikan hasil negatif palsu.
 12. Apakah boleh digunakan pada wanita hamil dan menyusui ? Karena studi reproduksi hewan belum dilakukan dengan Urea 14C. Juga tidak diketahui apakah Urea 14C dapat menyebabkan kerusakan janin saat diberikan kepada wanita hamil atau dapat mempengaruhi kapasitas reproduksi. Ketika pemberian Urea 14C kepada seorang wanita yang berpotensi mengandung anak dipertimbangkan, informasi harus selalu dicari tentang kehamilan.
Tidak diketahui apakah ini diekskresikan dalam ASI
 13. Apakah kapsul Urea 14C boleh digunakan pada anak – anak ? Belum ada studi klinik untuk penggunaan pada anak – anak. Konsultasikan pada dokter Anda
 14. Apakah boleh mengendarai dan menjalankan mesin selama minum Obat ini ? Tes ini tidak memiliki pengaruh atau diabaikan pada pengendara dan menjalankan mesin
 15. Efek yang tidak diinginkan yang mungkin terjadi Belum diketahui efek samping yang mungkin terjadi dan berhubungan dengan obat
 16. Tanda dan gejala kelebihan dosis serta apa yang harus dilakukan bila menggunakan Obat ini melebihi dosis yang dianjurkan ? Belum ada kasus overdosis yang dilaporkan. Dalam hal overdosis, pasien harus minum satu gelas air (150 mL) setiap jam untuk mempercepat ekskresi radioisotop. Ekskresi urea maksimum dicapai pada keluaran urin > 2,0mL / mnt.
 17. Bagaimana cara menyimpan Obat ini ? Simpan dibawah suhu 30°C, tertutup rapat.
 18. Nomor Izin Edar DKI
 19. Didaftarkan dan diimpor oleh : PT. Kaliroto
Sidorame 19-Surabaya, Jawa Timur
 20. Diproduksi oleh Shenzhen Zhonghe Headway Bio-Sci & Tech Co., Ltd
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HARUS DENGAN RESEP DOKTER