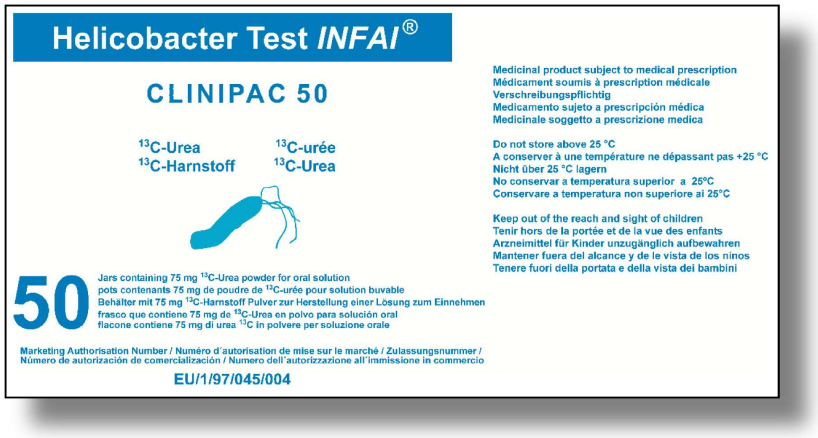
Helicobacter Test *INFAI*®
CLINIPAC 50

The approved breath test for detection of an infection with Helicobacter pylori



Due to the increasing demand, INFAI supplies from now on a large packaging size for clinical pharmacies and group practices offering the following advantages:

- Especially used for GPs, laboratory specialists and hospitals
- Cost-effective, cost savings of 40-53 % in comparison to the single test
- Contains test material for diagnosis of 50 patients
- Safe and reliable

For more information please contact:

***INFAI* GmbH**

Gottfried-Hagen-Straße 60-62, 51105 Cologne, Gernany
Phone: ++49 221 880 44 40, Fax: ++49 221 880 44 55
Email: mail@infai.com, Internet: http://www.infai.com

HelicobacterTest *INFAI*® CLINIPAC 50

50 jars with 75 mg ^{13}C-urea powder for oral solution

NAME OF THE MEDICINAL PRODUCT: Helicobacter Test INFAI®, 75 mg powder for oral solution
QUALITATIVE AND QUANTITATIVE COMPOSITION: 1 jar contains: active substance: ^{13}C-urea, powder, 75 mg
PHARMACEUTICAL FORM: Powder for oral solution
Therapeutic indications: Helicobacter Test INFAI® may be used for in vivo diagnosis of gastroduodenal Helicobacter pylori infection. **Posology and method of administration:** Helicobacter Test INFAI® is a breath test. Patients from the age of 12 and older take the contents of 1 jar (75 mg). The breath test is a single administration. For performance of the test procedure 200 ml 100% orange juice or 1g citric acid in 200 ml water for patients from the age of 12 and older (as a pre-administered test meal), as well as tap water (for dissolving the ^{13}C-urea powder) are necessary. The patient has to have fasted for over 6 hours, preferably overnight. The test procedure takes approximately 30 minutes. In case it is necessary to repeat the test procedure, this should not be done until the following day. The suppression of Helicobacter pylori might give false negative results. Therefore the test shall be used after at least four weeks without systemic antibacterial therapy and two weeks after last dose of acid antisecretory agents. Both might interfere with the Helicobacter pylori status. This is especially important after Helicobacter eradication therapy. It is important to follow the instructions for use described in section 6.6 adequately, otherwise the validity of the outcome will become questionable. **Contraindications:** The test must not be used in patients with documented or suspected gastric infection or atrophic gastritis, which might interfere with the urea breath test (please refer to section 4.2 - Posology and method of administration). **Special warnings and special precautions for use:** A positive test alone does not constitute indication for eradication therapy. Differential diagnosis with invasive endoscopic methods might be indicated in order to examine the presence of any other complicating conditions, e.g. ulcer, autoimmune gastritis and malignancies. There is insufficient data on the diagnostic liability of the Helicobacter Test INFAI® to recommend its use in patients with gastrectomy. In individual cases of A-gastritis (atrophic gastritis) the breath test may have false positive results; other tests may be required to confirm the Helicobacter pylori status. If the patient vomits during the test procedure, necessitating the repetition of the test, this should be done in fasted condition and not before the following day. **Interaction with other medicinal products and other forms of interaction:** Helicobacter Test INFAI® will be affected by all treatments interfering with Helicobacter pylori status or urease activity. **Pregnancy and lactation:** It is not expected that the test procedure may be harmful during pregnancy or lactation. It is recommended to take notice of the product information of eradication therapy products for their use during pregnancy and lactation. **Effects on ability to drive and use machines:** Helicobacter Test INFAI® has no influence on the ability to drive and use machines. **Undesirable effects:** None known: **Overdose:** Due to the fact that only 75 mg of ^{13}C-urea is delivered, an overdose is not expected. **List of excipients:** None **Incompatibilities:** Not applicable **Shelf-life:** 3 years **Special precautions for storage:** Do not store above 25 °C **Marketing authorisation holder:** INFAI Institut für biomedizinische Analytik und NMR-Imaging GmbH, Universitätsstraße 142, 44799 Bochum, Germany. **Marketing authorisation number:** EU/1/97/045/004. **Date of revision of the test:** April 2004