The European Agency for the Evaluation of Medicinal Products
Evaluation of Medicines for Human Use

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WITHDRAWAL OF THE MARKETING AUTHORISATION FOR THE MEDICINAL PRODUCT *PYLORI-CHEK – ^{13}C-urea* (EU/1/98/068/001)

- On 15 June 1998, the European Commission issued a Marketing Authorisation valid throughout the European Union for the medicinal product Pylori-Chek, which contains ^{13}C-urea. The pharmaceutical company responsible for this medicinal product is Alimenterics B V.
- On 17 April 2000, the Marketing Authorisation holder notified the European Commission about the Marketing Authorisation holder's decision to withdraw the Marketing Authorisation for Pylori-Chek.
- On 5 July 2000, the European Commission has adopted the decision withdrawing the Marketing Authorisation for the medicinal product for human use "PYLORI-CHEK - ^{13}C-urea". Pursuant to this decision the European Public Assessment Report for Pylori-Chek has been removed from the EMEA website.
- For information, it should be noted that at present there are still two Community Marketing Authorisations valid throughout the European Union for medicinal products containing ^{13}C-urea, i.e. Pylobactell (BSIA Ltd.) and Helicobacter Test INFAI (INFAI, Institut für biomedizinisiche Analytic und NMR Imaging GmbH) , in addition to nationally-authorised products.

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