

Pharma-Consulting
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Mr Doctor Eric Abadie
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

Subject: *Withdrawal of Gastromotal, (1-¹³C-caprylic acid) 90 mg, oral liquid C/724*

Dear Dr. Abadie,

For the withdrawal of initial marketing authorisation application

I would like to inform you that, at this point of time, *Infai GmbH* has taken the decision to withdraw the application for Marketing Authorisation of *Gastromotal, (1-¹³C-caprylic acid) 90 mg, oral liquid*, which was intended to be used for *in vivo diagnosis of solid phase gastric, half emptying time for gastric motility disorders*.

This withdrawal is based on the following reasons:

- *identification of major clinical issues*
- *the CHMP considers that the data provided do not allow the committee to conclude on a positive benefit risk balance*

We will continue with the clinical program and apply again for marketing approval. We will be asking for scientific advice from the EMEA, Rapporteur and Co-Rapporteur in order to fulfill all requirements regarding the next step in our clinical programm.

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

I agree for this letter to be published on the EMEA website.

Yours sincerely,