

Dr Tomas Salmonson
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13 September 2016

Subject: Withdrawal of Ertapenem Hospira (Ertapenem) 1 g powder for concentrate for solution for infusion - EMEA/H/C/004080/0000

Dear Dr Salmonson,

I would like to inform you that Hospira UK Limited has taken the decision to withdraw its Article 10(1) generic application for Marketing Authorisation for Ertapenem Hospira (Ertapenem) 1 g powder for concentrate for solution for infusion, which was intended to be used in the following indications:

Treatment

In paediatric patients (3 months to 17 years of age) and in adults for the treatment of the following infections when caused by bacteria known or very likely to be susceptible to ertapenem and when parenteral therapy is required:

- *Intra-abdominal infections*
- *Community acquired pneumonia*
- *Acute gynaecological infections*
- *Diabetic foot infections of the skin and soft tissue*

Prevention

In adults for the prophylaxis of surgical site infection following elective colorectal surgery.

This withdrawal is based on commercial reasons following an evaluation of the current market situation.

We reserve the right to make further submissions at a future date in these or other therapeutic indications.

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

Yours sincerely,

