



19 May 2022
EMA/CHMP/266696/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Ertapenem SUN

ertapenem

On 19 May 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ertapenem SUN, intended for the treatment of ertapenem-susceptible bacterial infection when parenteral therapy is required and prevention of surgical site infection following elective colorectal surgery.

The applicant for this medicinal product is SUN Pharmaceutical Industries (Europe) B.V.

Ertapenem SUN will be available as 1 g powder to be reconstituted into a concentrate for solution for infusion. The active substance of Ertapenem SUN is ertapenem, an antibacterial for systemic use (ATC code: J01DH03). Ertapenem belongs to the group of antibiotics known as ‘carbapenems’. It attaches to bacterial penicillin binding proteins, inhibiting cell wall synthesis and so killing the bacteria. Lists of bacteria species likely to be susceptible or resistant to ertapenem are presented in section 5.1 of the summary of product characteristics.

Ertapenem SUN is a generic of Invanz, which has been authorised in the EU since 18 April 2002. Since Ertapenem SUN is administered intravenously and is 100% bioavailable, a bioequivalence study versus the reference product Invanz was not required. A question and answer document on generic medicines can be found [here](#).

The full indication is:

Treatment

Ertapenem SUN is indicated 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 (see sections 4.4 and 5.1):

- Intra-abdominal infections
- Community acquired pneumonia

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion



- Acute gynaecological infections
- Diabetic foot infections of the skin and soft tissue

Prevention

Ertapenem SUN is indicated in adults for the prophylaxis of surgical site infection following elective colorectal surgery (see section 4.4 of the SmPC).

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.