

EMA/287844/2018 EMEA/H/C/000743

Ivemend (fosaprepitant)

An overview of Ivemend and why it is authorised in the EU

What is Ivemend and what is it used for?

Ivemend is a medicine for preventing nausea (feeling sick) and vomiting caused by chemotherapy cancer medicines.

It is used in adults and children from 6 months of age who are undergoing chemotherapy known to cause moderate or severe nausea and vomiting.

It contains the active substance fosaprepitant.

How is Ivemend used?

In adults, Ivemend is given as a slow infusion into a vein on the first day of chemotherapy. In children it may be given on the first day or on multiple days through a tube inserted into a large vein near the heart.

Ivemend must always be given together with other medicines that prevent nausea and vomiting, including a corticosteroid (such as dexamethasone) and a $5HT_3$ antagonist' (such as ondansetron). For more information about using Ivemend, see the package leaflet or contact your doctor or pharmacist.

How does Ivemend work?

The active substance in Ivemend, fosaprepitant, is a 'prodrug' of aprepitant. This means that it is converted to aprepitant in the body. Aprepitant is a neurokinin 1 (NK1) receptor antagonist. It stops a chemical in the body called 'substance P' from attaching to the NK1 receptors. When substance P attaches to these receptors, it causes nausea and vomiting. By blocking these receptors, Ivemend can prevent nausea and vomiting, which often happens during and after chemotherapy. Aprepitant has been authorised in the European Union (EU) as Emend since 2003.

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom Telephone +44 (0)20 3660 6000 Facsimile +44 (0)20 3660 5555 Send a question via our website www.ema.europa.eu/contact



An agency of the European Union

 $\ensuremath{\mathbb{C}}$ European Medicines Agency, 2018. Reproduction is authorised provided the source is acknowledged.

What benefits of Ivemend have been shown in studies?

A main study in 2,000 patients with cancer showed that Ivemend was as effective as a Emend another medicine approved for preventing nausea and vomiting. Around 72% of patients treated with either medicine did not have any nausea or vomiting over the five days after receiving chemotherapy.

What are the risks associated with Ivemend?

The most common side effects with Ivemend (seen in between 1 and 10 patients in 100) are increased liver enzymes, headache, hiccups, constipation, dyspepsia (heartburn), loss of appetite and fatigue (weakness or tiredness). For the full list of side effects reported with Ivemend, see the package leaflet.

Ivemend must not be used at the same time as pimozide (used to treat mental illness), terfenadine and astemizole (used to treat allergy symptoms) and cisapride (used to relieve certain stomach problems). For the full list of restrictions, see the package leaflet.

Why is Ivemend authorised in the EU?

A main study showed that Ivemend was as effective as Emend at preventing nausea and vomiting in patients undergoing chemotherapy and its side effects are considered to be manageable. The European Medicines Agency therefore decided that Ivemend's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Ivemend?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Ivemend have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Ivemend are continuously monitored. Side effects reported with Ivemend are carefully evaluated and any necessary action taken to protect patients.

Other information about Ivemend

Ivemend received a marketing authorisation valid throughout the EU on 11 January 2008.

Further information on Ivemend can be found on the Agency's website: <u>ema.europa.eu/Find</u> <u>medicine/Human medicines/European public assessment reports</u>.

This overview was last updated in 05-2018.