EMA/297995/2020
EMEA/H/C/005048

Xenleta (*lefamulin*)

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

What is Xenleta and what is it used for?

Xenleta is an antibiotic used in adults to treat community-acquired pneumonia (a lung infection caught outside of hospital) when other antibiotic medicines are not suitable or do not work.

Xenleta contains the active substance lefamulin.

How is Xenleta used?

Xenleta can only be obtained with a prescription, and official guidelines on the use of antibiotics should be considered by the prescribing doctor.

Xenleta can be given by mouth as tablets or by infusion (drip) into a vein.

The recommended dose for Xenleta tablets is 600 mg every 12 hours, taken at least 1 hour before or 2 hours after a meal. The duration of treatment is 5 days.

Xenleta infusion is given over 1 hour at a dose of 150 mg every 12 hours. Treatment may be switched to Xenleta tablets and the total duration of treatment is 7 days.

For more information about using Xenleta, see the package leaflet or contact your doctor or pharmacist.

How does Xenleta work?

The active substance in Xenleta, lefamulin, belongs to a group of medicines called pleuromutilins. Lefamulin interferes with bacterial RNA (genetic material), blocking the production of bacterial proteins. This prevents the bacteria from multiplying and they eventually die.

What benefits of Xenleta have been shown in studies?

Xenleta was tested in two main studies involving 1,282 adults with community-acquired pneumonia. Both studies showed that Xenleta was as effective as moxifloxacin (another antibiotic).

In the first study patients were either given Xenleta infusion and then switched to Xenleta tablets, or moxifloxacin infusion and then switched to moxifloxacin tablets. In both cases, treatment with infusion

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

continued for at least 3 days and the total duration of treatment was 5 to 7 days for Xenleta and 7 to 10 days for moxifloxacin. Cure rates were similar in the two groups: 82% of patients treated with Xenleta and 84% of those treated with moxifloxacin had no signs of infection 5 to 10 days after the last dose.

In the second study, patients were given Xenleta tablets for 5 days or moxifloxacin tablets for 7 days. Xenleta was as effective as moxifloxacin at curing the infection: 88% of patients treated with Xenleta and 89% of those treated with moxifloxacin had no signs of infection 5 to 10 days after the last dose.

What are the risks associated with Xenleta?

The most common side effects with Xenleta (which may affect up to 1 in 10 people) are redness, pain or swelling at the site of the infusion; diarrhoea, nausea (feeling sick), or vomiting (mostly with tablets); raised levels of liver enzymes (a sign of liver problems), headache, hypokalaemia (low potassium levels in blood), and insomnia (difficulty sleeping).

The most common serious reaction, in less than 1 in 10 patients, is atrial fibrillation (an abnormal rapid rhythm of the upper chambers of the heart).

Xenleta should not be used in patients who are hypersensitive (allergic) to the active substance in Xenleta or any other pleuromutilin antibiotic. It should not be taken together with certain medicines that might cause interactions that can alter the effect of Xenleta or the other medicines.

Xenleta must not be given to patients with prolonged QT interval (abnormal electrical activity of the heart that affects its rhythm) or who take medicines that prolong QT interval, or who have a salt imbalance in the blood (especially low potassium levels). It should also not be given to patients with heart problems such as abnormal heart rhythm or heart failure (when the heart does not work well enough).

For the full list of side effects and restrictions with Xenleta, see the package leaflet.

Why is Xenleta authorised in the EU?

Studies found that Xenleta was as effective as moxifloxacin at treating community-acquired pneumonia. Its side effects were considered manageable. Therefore, the European Medicines Agency decided that Xenleta'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 Xenleta?

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

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

Other information about Xenleta

Xenleta received a marketing authorisation valid throughout the EU on 27 July 2020.

Further information on Xenleta can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/xenleta.

This overview was last updated in 07-2020.