

Package leaflet: Information for the user

Xenleta 600 mg film-coated tablets lefamulin

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Xenleta is and what it is used for
2. What you need to know before you take Xenleta
3. How to take Xenleta
4. Possible side effects
5. How to store Xenleta
6. Contents of the pack and other information

1. What Xenleta is and what it is used for

Xenleta is an antibiotic medicine containing the active substance lefamulin. It belongs to a group of medicines called 'pleuromutilins'.

Lefamulin works by killing certain bacteria which cause infections.

Xenleta is used to treat adults who have bacterial infections in the lung, also known as pneumonia, when other treatments for pneumonia are not considered to be suitable.

2. What you need to know before you take Xenleta

Do not take Xenleta

- if you are **allergic to lefamulin** or any of the other ingredients of this medicine (listed in section 6)
- if you are **allergic to other medicines** from the pleuromutilin class
- if you are **taking certain medicines** that might interact with Xenleta. This is because some medicines may stop Xenleta working or lead to side effects if they are given with Xenleta. See below under **Other medicines and Xenleta** for examples.
- if you are **taking medicines** that can cause changes in the heart's electrical activity seen with an ECG (see below under **Other medicines and Xenleta**). This is because lefamulin can cause a condition called QT interval prolongation i.e. abnormal electrical activity that affects the heart's rhythm.
- if you have a **salt imbalance** in the blood (especially low levels of potassium in the blood)
- if you have or have had an **irregular heart rhythm or an abnormal ECG finding called QT prolongation**
- if you have a **very slow heart beat** (bradycardia)
- if your **heart does not work well enough** (heart failure)

Warnings and precautions

Talk to your doctor, pharmacist, or nurse before you are given Xenleta

- if you have **kidney failure** and require dialysis.
- if you have cirrhosis (**severe liver disease.**)

If any of these apply to you, or if you are not sure, tell your doctor before taking Xenleta.

If you develop severe diarrhoea during or after taking Xenleta tablets, talk to your doctor because you may need to stop your medicine, or you may need to take another medicine to treat the diarrhoea. Antibiotics can lead to excessive growth of certain bacteria in your bowel (gut) that can damage the bowel and cause severe diarrhoea.

If you develop yellow skin (jaundice) or the white of your eyes turn yellow (scleral icterus), talk to your doctor because you may need to stop taking Xenleta or other medicines.

Other infections

There is a small possibility that you may get a different infection caused by another bacteria during or after treatment with Xenleta. Your doctor will monitor you closely for any new infections and give you another treatment if necessary.

Children and adolescents

Xenleta is **not recommended** for use in children and adolescents less than 18 years old.

Other medicines and Xenleta

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, as some of them could affect or be affected by Xenleta. The lists below provide only some examples of medicines that should be avoided while taking lefamulin or for which caution is needed. Your doctor will advise you if lefamulin is suitable for you.

You must not take any of the following medicines with lefamulin:

- carbamazepine, phenytoin, primidone (for epilepsy)
- efavirenz, ritonavir- (for HIV)
- St. John's Wort, an herbal remedy (for depression or low mood)
- bosentan, diltiazem, amiodarone, sotalol, quinidine, procainamide (for angina, high blood pressure or heart rhythm disturbances)
- rifampicin, clarithromycin, erythromycin (for bacterial infections)
- fluconazole, itraconazole, posaconazole, voriconazole (for fungal infections)
- ketoconazole (for Cushing's disease)
- repaglinide (for diabetes)
- nefazodone, amitriptylline or pimozide (for depression or other mental illness)

Your doctor may need to adjust the dose of some medicines while you are taking lefamulin. These medicines include:

- * alprazolam, midazolam, triazolam or other drugs called benzodiazepines (for anxiety)
- * alfentanil (an opioid for pain)
- * vardenafil (for erectile dysfunction)
- * ibrutinib (for certain types of cancer)
- * lovastatin, rosuvastatin or simvastatin (to reduce cholesterol levels)
- * metformin (for diabetes)
- * zolpidem (for insomnia)
- * ethinyl oestradiol (used in birth control pills)
- * verapamil (for high blood pressure)

Xenleta with food and drink

Xenleta should be taken on an empty stomach, at least 1 hour before or 2 hours after a meal. This is because food and some drinks can affect the way medicines work.

You must not eat grapefruit or drink grapefruit juice while on treatment with Xenleta as it might interact with Xenleta and increase side effects.

Pregnancy, breast-feeding

Do not take Xenleta if you are pregnant or breast-feeding. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Taking Xenleta will not influence the ability to drive or use machines.

Xenleta contains sodium

This medicine contains less than 1 mmol sodium (23mg) per tablet, that is to say essentially, 'sodium free'.

3. How to take Xenleta

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one 600-mg Xenleta tablet taken every 12 hours for 5 days. The tablets should be swallowed whole with water.

Xenleta tablets may also be taken after starting treatment with Xenleta infusion via an intravenous drip. The number of days you then need to take Xenleta tablets will depend on how many days you had treatment by a drip.

Your doctor will tell you for how long you should take Xenleta. It is important that you complete the course.

If you take more Xenleta than you should

If you accidentally take too many tablets, contact your doctor or pharmacist.

If you forget to take Xenleta

Do not take a double dose to make up for a forgotten tablet. You should continue with your course from the next scheduled dose.

If you stop taking Xenleta

Take the complete course of tablets prescribed by your doctor, even if you begin to feel better before you have finished them all. If you stop taking the tablets too soon, the infection may return, or your condition may get worse.

Some bacteria may remain and become resistant to antibiotics if you do not complete the course or if you do not take your tablets at the right time. This can result in the infection returning or in the antibiotic not working if the infection returns.

If you get a side effect that concerns you, tell a doctor immediately to get advice before taking the next dose.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common: may affect up to 1 in 10 people

- * low potassium levels in your blood (hypokalaemia), which can cause muscle weakness, twitching or abnormal heart rhythm
- * difficulty sleeping (insomnia)
- * headache
- * change of the heart rhythm (seen on an ECG, which monitors the electrical activity of the heart)
- * diarrhoea
- * feeling sick (nausea) or being sick (vomiting)
- * increase of a special liver enzyme in the blood (transaminases)

Uncommon: may affect up to 1 in 100 people

- * inflammation of the bowel causing diarrhoea (colitis), due to an infection by a type of bacteria called *Clostridioides difficile* (previously called *Clostridium difficile*)
- * fungal (yeast) infection of the throat and mouth (thrush or candida infection)
- * fungal (yeast) infection of the vagina and vulva (thrush or candida infection)
- * reduction in red blood cells (anaemia), which can make the skin pale and cause weakness or breathlessness
- * reduction in blood platelets (blood cells which help the blood to clot), which increases your risk of bleeding or bruising
- * feeling anxious
- * dizziness
- * feeling tired or drowsy
- * irregular heartbeat or rhythm or palpitations
- * pain at the back of the nose and throat
- * stomach pain, pain in the abdomen or around the stomach
- * constipation
- * indigestion, stomach acidity (heartburn), or inflammation of the stomach lining (gastritis)
- * increase of a liver enzyme in the blood (gamma-glutamyl transferase and alkaline phosphatase)
- * increase in a muscle enzyme in the blood (creatine phosphokinase)
- * difficulty in urinating or in fully emptying your bladder (urinary retention)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V](#). By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Xenleta

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information**What Xenleta contains**

- The active substance is lefamulin. Each tablet contains lefamulin acetate equivalent to 600 mg of lefamulin.
- The other ingredients are colloidal silicon dioxide (E551), croscarmellose sodium (E468), magnesium stearate (E572), mannitol (E421), microcrystalline cellulose (E460), povidone K30, talc (E553b).
- Film Coating: black iron oxide (E172), indigo carmine lake (E132), macrogol, poly (vinyl alcohol) (E1203), propylene glycol, shellac (E904), talc, titanium dioxide (E171).

What Xenleta looks like and contents of the pack

Xenleta 600 mg film-coated tablets are blue, oval, film-coated tablets printed with “LEF 600” in black on one side.

Xenleta film-coated tablets are provided in blister packs of 10 tablets.

Marketing Authorisation Holder

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Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>.