

## Package leaflet: Information for the patient

### Xerava 100 mg powder for concentrate for solution for infusion eravacycline

**Read all of this leaflet carefully before you receive 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 or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

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

#### **1. What Xerava is and what it is used for**

##### **What Xerava is**

Xerava is an antibiotic medicine that contains the active substance eravacycline. It belongs to a group of antibiotics called 'tetracyclines' which work by stopping the growth of certain infectious bacteria.

##### **What Xerava is used for**

Xerava is used to treat adults with a complicated infection in the abdomen.

#### **2. What you need to know before you are given Xerava**

##### **You must not receive Xerava**

- if you are allergic to eravacycline or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to any tetracycline antibiotics (e.g., minocycline and doxycycline) because you may also be allergic to eravacycline.

##### **Warnings and precautions**

Talk to your doctor or nurse before you receive Xerava if you are concerned about any of the following:

##### Anaphylactic reactions

Anaphylactic (allergic) reactions have been reported with other tetracycline antibiotics. These can develop suddenly and can potentially be life-threatening. **Seek urgent medical attention** if you suspect you have an anaphylactic reaction whilst receiving Xerava. Symptoms to look out for include rash, swelling of the face, feeling lightheaded or faint, tightness of the chest, breathing difficulties, fast heartbeat, or losing consciousness (see also section 4).

### Diarrhoea

Talk to your doctor or nurse if you are suffering from diarrhoea before being given Xerava. If you develop diarrhoea during or after your treatment, **tell your doctor straight away**. Do not take any medicine to treat your diarrhoea without first checking with your doctor (see also section 4).

### Infusion site reactions

Xerava is given by an infusion (drip) directly into your vein. **Tell your doctor or nurse** if you notice any of the following at the site of infusion during or after your treatment: redness of the skin, rash, inflammation, or pain or tenderness.

### New infection

Although Xerava fights certain bacteria, other bacteria and fungi may continue to grow. This is called 'overgrowth' or 'superinfection'. Your doctor will monitor you closely for any new infections or stop treatment with Xerava and give you another treatment if necessary.

### Pancreatitis

Severe pain in the abdomen and back with fever may be signs of inflammation of the pancreas. Tell your doctor or nurse if you notice any of these side effects during your treatment with Xerava.

### Liver problems

Talk to your doctor if you have liver problems or if you are overweight, particularly if you are also taking itraconazole (a medicine to treat fungal infections), ritonavir (a medicine used to treat viral infections) or clarithromycin (an antibiotic) as your doctor will monitor you for side effects.

## **Children and adolescents**

This medicine should not be used in children and adolescents under the age of 18 years as it has not been studied enough in these populations. Xerava must not be used in children below 8 years of age because it can cause permanent effects on their teeth such as discolouration.

## **Other medicines and Xerava**

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines including rifampicin and clarithromycin (antibiotics), phenobarbital, carbamazepine and phenytoin (used to treat epilepsy), St. John's Wort (a herbal remedy used for treatment of depression and anxiety) itraconazole (a medicine to treat fungal infections), ritonavir, atazanavir, lopinavir and saquinavir (medicines used to treat viral infections), and cyclosporine (a medicine used to suppress the immune system).

## **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before receiving this medicine. Xerava is not recommended for use during pregnancy as it can:

- permanently stain your unborn child's teeth
- delay the natural formation of the bones of your unborn child.

It is not known if Xerava passes into breast milk. Long-term use of other similar antibiotic medicines by breast-feeding mothers can stain the child's teeth permanently. Ask your doctor for advice before breast-feeding your baby.

## **Driving and using machines**

Xerava may affect your ability to drive or use machines safely. Do not drive or use machines if you feel dizzy, light-headed or unsteady after receiving this medicine.

### **3. How you will be given Xerava**

Xerava will be given to you by a doctor or nurse.

The recommended dose for adults is based on body weight and is 1 mg/kg every 12 hours. Your doctor may increase your dose (1.5 mg/kg every 12 hours) if you are taking other medicines including rifampicin, phenobarbital, carbamazepine, phenytoin, or St. John's Wort.

It will be given to you through a drip directly into a vein (intravenously) over approximately 1 hour.

A course of treatment usually lasts for 4 to 14 days. Your doctor will decide how long you should be treated for.

#### **If you are given more Xerava than you should**

Xerava will be given to you in hospital by a doctor or nurse. It is, therefore, unlikely that you will be given too much. Tell your doctor or nurse immediately if you are concerned that you may have been given too much Xerava.

#### **If you miss a dose of Xerava**

Xerava will be given to you in hospital by a doctor or nurse. It is, therefore, unlikely that you will miss a dose. Tell your doctor or nurse immediately if you are concerned that you may have missed a dose.

### **4. Possible side effects**

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

**Seek urgent medical attention** if you suspect you have an anaphylactic reaction, or develop any of the following symptoms, whilst receiving Xerava:

- Rash
- Swelling of the face
- Feeling lightheaded or faint
- Tightness of the chest
- Breathing difficulties
- Fast heartbeat
- Losing consciousness

**Tell your doctor or nurse straightaway** if you develop diarrhoea during or after your treatment. Do not take any medicine to treat your diarrhoea without first checking with your doctor.

#### **Other side effects may include:**

**Common** (may affect up to 1 in 10 people):

- Nausea
- Vomiting
- Inflammation and pain caused by blood clots at the injection site (thrombophlebitis)
- Inflammation of a vein causing pain and swelling (phlebitis)
- Redness or swelling at the site of the injection

**Uncommon** (may affect up to 1 in 100 people):

- Diarrhoea
- Allergic reaction
- Inflammation of the pancreas which causes severe pain in the abdomen or back (pancreatitis)
- Rash
- Dizziness
- Headache
- Increased sweating
- Abnormal blood test results for liver

Tell your doctor or nurse if you have any of these side effects.

#### Other tetracycline antibiotics

Other side effects have been reported with other tetracycline antibiotics including minocycline and doxycycline. These include sensitivity to light, headaches, vision problems, or abnormal blood tests. Tell your doctor or nurse if you notice any of these during your treatment with Xerava.

#### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, website: <http://www.mhra.gov.uk/yellowcard> or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. How to store Xerava**

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 vial label and carton after 'EXP'. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C). Keep the vial in the carton in order to protect from light.

Once the powder has been made into a solution and diluted ready for use, it should be given to you immediately. If not, it may be stored at room temperature and used within 12 hours.

Reconstituted Xerava should be a clear, pale yellow to orange solution. The solution should not be used if it appears to contain any particles or the solution is cloudy.

#### **6. Contents of the pack and other information**

##### **What Xerava contains**

- The active substance is eravacycline. Each vial contains 100 mg of eravacycline.
- The other ingredients are mannitol (E421), hydrochloric acid (for pH adjustment) and sodium hydroxide (for pH adjustment).

##### **What Xerava looks like and contents of the pack**

Xerava is a pale yellow to dark yellow cake in a 10 mL glass vial. The powder for concentrate for solution for infusion (powder for concentrate) will be reconstituted in the vial with 5 mL of water for injections or with 5 mL sodium chloride 9 mg/mL (0.9%) solution for injection. The reconstituted solution will be withdrawn from the vial and added to an infusion bag of sodium chloride 9 mg/mL (0.9%) solution for injection in the hospital.

Xerava is available in packs containing 1 vial, 10 vials or multipacks comprising 12 cartons, each containing 1 vial.

Not all pack sizes may be marketed.

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