

## Package leaflet: Information for the patient

### Xermelo 250 mg film-coated tablets telotristat ethyl

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

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

##### **What Xermelo is**

This medicine contains the active substance telotristat ethyl.

##### **What Xermelo is used for**

This medicine is used in adults with a condition called ‘carcinoid syndrome’. This is when a tumour, called a ‘neuroendocrine tumour’, releases a substance called serotonin into your bloodstream.

Your doctor will prescribe this medicine if your diarrhoea is not well controlled with injections of other medicines called ‘somatostatin analogues’ (lanreotide or octreotide). You should keep having injections of these other medicines when taking Xermelo.

##### **How Xermelo works**

When the tumour releases too much serotonin into your bloodstream you can get diarrhoea. This medicine works by reducing the amount of serotonin made by the tumour. It will reduce your diarrhoea.

#### **2. What you need to know before you take Xermelo**

##### **Do not take Xermelo**

- if you are allergic to telotristat or any of the other ingredients of this medicine (listed in section 6).

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

Talk to your doctor or pharmacist before taking Xermelo:

- if you have liver problems. This is because this medicine is not recommended for use in patients with severe liver problems. Your doctor may decide to decrease your daily dose of Xermelo in cases where your liver problems are considered mild or moderate. Your doctor will also monitor your liver.

- if you have end-stage kidney disease or are on dialysis. This is because this medicine has not been tested in patients with end-stage kidney disease, requiring dialysis.

### ***Look out for side effects***

Tell your doctor straight away if you notice any of the following signs and symptoms that suggest that your liver may not be working properly:

- feeling or being sick (unexplained nausea or vomiting), abnormally dark urine, yellow skin or eyes, pain in the upper right belly.

Your doctor will do blood tests to check your liver and will decide whether you should keep taking this medicine.

Talk to your doctor or pharmacist:

- if you feel down, depressed, or if you feel you have no interest or take any pleasure in doing your normal activities, whilst taking this medicine, as depression, depressed mood and decreased interest have been reported in patients treated with telotristat.
- if you have signs of constipation, as telotristat reduces the number of your bowel movements.

### ***Tests***

- Your doctor may carry out blood tests before you start taking this medicine and while you are taking it. This is to check that your liver is working normally.

### **Children and adolescents**

This medicine is not recommended in patients below 18 years old. This is because the medicine has not been studied in this age group.

### **Other medicines and Xermelo**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Xermelo can affect the way some other medicines work, or other medicines can affect the way Xermelo works. This could mean that your doctor needs to change the dose(s) that you take. You should tell your doctor about every medicine. This includes:

- medicines for diarrhoea. Xermelo and these medicines reduce the number of your bowel movements and taken together, they can cause severe constipation. Your doctor may need to change the dose of your medicines.
- medicines used to treat epilepsy, such as valproic acid.
- medicines used to treat your neuroendocrine tumour, such as sunitinib or everolimus.
- medicines to treat depression, such as bupropion or sertraline.
- medicines used to avoid transplant rejection, such as cyclosporine.
- medicines used to lower cholesterol levels, such as simvastatin.
- oral contraceptives, such as ethinyloestradiol.
- medicines used to treat high blood pressure, such as amlodipine.
- medicines used to treat some types of cancers, such as irinotecan, capecitabine and flutamide.
- medicines used to reduce the chance of a blood clot forming, such as prasugrel.
- octreotide. If you need treatment with octreotide subcutaneous injections, you should have your injection at least 30 minutes after taking Xermelo.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should not take this medicine if you are pregnant or might become pregnant. It is not known how telotristat may affect the baby.

Women should use effective methods of contraception while taking this medicine.

You should not breast-feed if you are taking Xermelo, as this medicine may be passed on to your baby and may harm your baby.

### **Driving and using machines**

Xermelo may have a small effect on your ability to drive or use any tools or machines. If you feel tired, you should wait until you feel better before driving or using any tools or machines.

### **Xermelo contains lactose**

Xermelo contains lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

### **Xermelo contains sodium**

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

## **3. How to take Xermelo**

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

### **How much to take**

The recommended dose is one tablet (250 mg) three times a day. The maximum dose of Xermelo is 750 mg in 24 hours.

Your doctor will decide for how long you should take Xermelo.

If you have liver problems, your doctor may decide to reduce your daily dose of Xermelo.

### **Taking this medicine**

- Always take this medicine with a meal or some food.
- You should keep having injections of somatostatin analogues (lanreotide or octreotide) when taking Xermelo.

### **If you take more Xermelo than you should**

You may feel sick or be sick, have diarrhoea or stomach ache. Talk to a doctor. Take the medicine pack with you.

### **If you forget to take Xermelo**

If you forget to take a dose, take your next dose when it is due, skipping the missed dose.

Do not take a double dose to make up for a forgotten dose.

### **If you stop taking Xermelo**

Do not stop taking Xermelo without talking with your doctor.

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

## **4. Possible side effects**

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

### **Tell your doctor immediately if you notice any of the following side effects:**

- feeling or being sick, abnormally dark urine, yellow skin or eyes, pain in the upper right belly. These may be signs that your liver is not working properly. This might also be shown by changes in your blood test results, such as an increase of liver enzymes: gamma-glutamyl transferase (very common, may affect more than 1 in 10 people), transaminases and blood alkaline phosphatase (common, may affect up to 1 in 10 people).

### **Other side effects**

Tell your doctor, pharmacist or nurse if you notice any of the following side effects:

**Very common side effects (may affect more than 1 in 10 people):**

- Belly (abdominal) pain
- Feeling tired or weak (fatigue)
- Feeling sick (nausea)

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

- Wind
- Fever
- Headache
- Constipation
- Swollen stomach
- Decreased appetite
- Swelling (build-up of fluid in the body)
- Depression, you may experience decreased self-esteem, lack of motivation, sadness or low mood

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

- Impacted stools (bowel obstruction, faecaloma), you may experience, constipation, watery diarrhoea, pale skin (anaemia), nausea, vomiting, weight loss, back pain or stomach pains particularly after eating or a reduction in passing water (urination).

**Tell your doctor immediately** if you experience any of the following side effects:

- Breathing problems, rapid heartbeat, fever, incontinence (uncontrollable urination), confusion, dizziness or agitation.

Tell your doctor, pharmacist or nurse if you notice any of the side effects listed above.

**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 Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](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 Xermelo**

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 the blister after EXP. The expiry date refers to the last day of that month.

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.

This medicine does not require any special storage conditions.

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

**What Xermelo contains**

- The active substance is telotristat ethyl. Each film-coated tablet contains telotristat etiprate equivalent to 250 mg telotristat ethyl.
- The other ingredients are:  
Tablet core: lactose (see section 2 under ‘Xermelo contains lactose’), hydroxypropylcellulose, croscarmellose sodium, magnesium stearate, and colloidal anhydrous silica.  
Film-coating: poly(vinyl alcohol) (E1203), titanium dioxide (E171), macrogol 3350 (E1521) and talc (E553b).

**What Xermelo looks like and contents of the pack**

The tablets are white to off-white, film-coated and oval shaped. Each tablet is approximately 17 mm long by 7.5 mm wide with ‘T-E’ debossed on one side and ‘250’ debossed on the other. The tablets are packaged in a PVC/PCTFE/PVC/Al blister. The blisters are packaged in a carton.

Cartons of 90 and 180 tablets. Not all pack sizes may be marketed.

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