

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

### 1. Why am I using XERMELO?

XERMELO contains the active ingredient telotristat ethyl. XERMELO is used to treat a condition called 'carcinoid syndrome'.

For more information, see Section [1. Why am I using XERMELO?](#) in the full CMI.

### 2. What should I know before I use XERMELO?

Do not use if you have ever had an allergic reaction to XERMELO or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use XERMELO?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with XERMELO and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use XERMELO?

- The recommended dose is one tablet three times a day. If needed, your doctor may tell you to take a different dose.
- Swallow the tablets with food or a meal at about the same time each day.

More instructions can be found in Section [4. How do I use XERMELO?](#) in the full CMI.

### 5. What should I know while using XERMELO?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Keep having injections of somatostatin analogues (lanreotide or octreotide) when taking XERMELO.</li><li>• Remind your doctor, pharmacist, dentist and any other healthcare professionals that treat you that you are taking XERMELO.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop taking your medicine or lower the dosage without checking with your doctor</li><li>• Do not take XERMELO to treat any other complaints unless your doctor tells you to.</li><li>• Do not give your medicine to anyone else, even if they have the same condition as you.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful driving or operating machinery until you know how XERMELO affects you.</li><li>• This medicine may cause fatigue in some people. If you have this symptom, do not drive, operate machinery or do anything else that could be dangerous.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Be careful consuming alcohol until you know how XERMELO affects you.</li><li>• Discuss with your healthcare professional the use of XERMELO with alcohol.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep your tablets in a cool dry place where the temperature stays below 30°C.</li><li>• Keep your tablets in the pack until it is time to take them.</li></ul>

For more information, see Section [5. What should I know while using XERMELO?](#) in the full CMI.

### 6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking XERMELO. You may need medical attention if you get some of the side effects. In particular, if you experience any of the following: breathing problems, rapid heartbeat, fever, incontinence (uncontrollable urination), confusion, dizziness, agitation, abnormally dark urine, yellow skin or eyes, pain in the upper right belly. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

- ▼ 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. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

# Xermelo®

Active ingredient(s): *telotristat ethyl*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using XERMELO. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using XERMELO.**

**Where to find information in this leaflet:**

- [1. Why am I using XERMELO?](#)
- [2. What should I know before I use XERMELO?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use XERMELO?](#)
- [5. What should I know while using XERMELO?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I using XERMELO?

**XERMELO contains the active ingredient telotristat ethyl.** XERMELO is tryptophan hydroxylase inhibitor that works by reducing the amount of serotonin made by the tumour.

**XERMELO is used in adults for the treatment of a condition called 'carcinoid syndrome'.** This is when a tumour, called a 'neuroendocrine tumour', releases a hormone called serotonin into your bloodstream.

When the tumour releases too much serotonin into your bloodstream you can get symptoms such as:

- diarrhoea and stomach (abdominal) pain
- flushing of your skin, particularly the face
- low blood pressure
- rash
- weight loss

The symptoms are not the same for everyone.

Your doctor will prescribe XERMELO:

- when your tumour has spread to different parts of your body
- and 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.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

### 2. What should I know before I use XERMELO?

#### Warnings

**Do not use XERMELO if:**

- you are allergic to telotristat ethyl, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

**Check with your doctor if you:**

- have allergies to any other medicines, foods, preservatives or dyes.
- have any other medical conditions, such as:
  - 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.
  - 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.
- are pregnant or plan to become pregnant.
- are breast-feeding.
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

#### Pregnancy and breastfeeding

**Check with your doctor if you are pregnant or intend to become pregnant.** It is not known how XERMELO may affect the baby.

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

**Talk to your doctor if you are breastfeeding or intend to breastfeed.** It is unknown if the active ingredient in XERMELO passes into breast milk and there is a possibility that your baby may be affected.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and XERMELO may interfere with each other. Tell your doctor or pharmacist if you are taking, have taken or are planning to take any of the following:

- 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, carbamazepine and topiramate.
- medicines used to treat your neuroendocrine tumour, such as sunitinib or everolimus.
- medicines to treat depression, such as sertraline.
- medicine to treat smoking cessation, such as bupropion.
- medicines used to avoid transplant rejection, such as ciclosporin.
- medicines used to lower cholesterol levels, such as simvastatin and atorvastatin.
- oral contraceptives, such as ethinyloestradiol.
- medicines used to treat high blood pressure, such as amlodipine, nifedipine, felodipine, verapamil and diltiazem.
- 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 injection, you should have your injection at least 30 minutes after taking XERMELO.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect XERMELO.**

These medicines may be affected by XERMELO or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

## 4. How do I use XERMELO?

### How much to take

- **The recommended dose is one tablet three times a day.** If needed, your doctor may tell you to take a different dose.
- If your symptoms do not improve, talk to your doctor.
- Follow the instructions provided and use XERMELO until your doctor tells you to stop. This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

### When to take XERMELO

- **Take your medicine at about the same time each day.**

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

### How to take XERMELO

- **Swallow the tablets with food or a meal.**

### If you forget to use XERMELO

XERMELO should be used regularly at the same time each day. If you miss your dose at the usual time, take your next dose when it is due, skipping the missed dose.

**Do not take a double dose to make up for the dose you missed.**

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

## If you use too much XERMELO

If you think that you have used too much XERMELO, you may need urgent medical attention.

### You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using XERMELO?

### Things you should do

- **You should keep having injections of somatostatin analogues (lanreotide or octreotide) when taking XERMELO.**
- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking XERMELO.
- Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.
- **If you are about to have any blood tests, tell your doctor that you are taking this medicine.** It may interfere with the results of some tests.
- **Keep all of your doctor's appointments so that your progress can be checked.** 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.

### Call your doctor straight away if you:

- **If you become pregnant while taking this medicine.**
- If your symptoms do not improve.

### Things you should not do

- Do not take XERMELO to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not stop taking your medicine or lower the dosage without checking with your doctor.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how XERMELO affects you.**

This medicine may cause fatigue in some people. If you have this symptom, do not drive, operate machinery or do anything else that could be dangerous.

### Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

**Keep your tablets in the pack until it is time to take them.** If you take the tablets out of the pack, they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Store it in away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

#### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

#### Less serious side effects

Less serious side effects	What to do
<p><b>General Body:</b></p> <ul style="list-style-type: none"> <li>• Feeling tired or weak (fatigue)</li> <li>• Fever</li> <li>• Decreased appetite</li> <li>• Depression. You may experience decreased self-esteem, lack of motivation, sadness or low mood</li> <li>• Swelling (build-up of fluid in the body)</li> <li>• Headache</li> <li>• Pale skin (anaemia)</li> </ul> <p><b>Urinary or Digestive Tract:</b></p> <ul style="list-style-type: none"> <li>• Feeling sick (nausea)</li> <li>• Stomach (abdominal) pain</li> <li>• Wind</li> <li>• Constipation</li> <li>• Swollen stomach</li> <li>• Vomiting, weight loss</li> <li>• Impacted stools (faecaloma), constipation, watery diarrhoea</li> <li>• Back pain or stomach pains particularly after eating or a reduction in passing water (urination)</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

#### Serious side effects

Serious side effects	What to do
<p><b>Allergic Reaction:</b></p> <ul style="list-style-type: none"> <li>• Shortness of breath</li> <li>• Wheezing or difficulty breathing</li> <li>• Swelling of the face, lips, tongue or other parts of the body</li> <li>• Rash, itching or hives on the skin</li> </ul> <p><b>Heart and Lungs:</b></p>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you</b></p>

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• Breathing problems, rapid heartbeat</li> </ul> <p><b>General Body:</b></p> <ul style="list-style-type: none"> <li>• High or persistent fever</li> <li>• Confusion, dizziness or agitation</li> </ul> <p><b>Urinary or Digestive Tract:</b></p> <ul style="list-style-type: none"> <li>• Incontinence (uncontrollable urination)</li> </ul> <p><b>Liver:</b></p> <ul style="list-style-type: none"> <li>• Feeling or being sick, abnormally dark urine, yellow skin or eyes, pain in the upper right belly</li> </ul> <p>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.</p>	<p><b>notice any of these serious side effects.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

#### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

#### What XERMELO contains

<b>Active ingredient (main ingredient)</b>	250 mg of telotristat ethyl (free base) equivalent to 327.9 mg telotristat etiprate
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>• colloidal anhydrous silica</li> <li>• croscarmellose sodium</li> <li>• hypromellose</li> <li>• lactose</li> <li>• magnesium stearate</li> <li>• polyvinyl alcohol</li> <li>• titanium dioxide (E171)</li> <li>• macrogol 3350</li> <li>• purified talc (E553b).</li> </ul>
<b>Potential allergens</b>	<p>Contains Lactose.</p> <p>This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.</p>

**Do not take this medicine if you are allergic to any of these ingredients.**

**What XERMELO looks like**

XERMELO 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 blisters are packaged in a carton of 90 tablets.

AUST R 291734

**Who distributes XERMELO**

Clinect Pty Ltd,

120-132 Atlantic Drive,

Keysborough, VIC 3173,

Australia

Free Call Australia: 1800 899 005

This leaflet was prepared in October 2022.