

# Isturisa

## 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 TAKING ISTURISA?

Isturisa contains the active ingredient osilodrostat. Isturisa is used in adults to treat endogenous Cushing's syndrome.

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

### 2. WHAT SHOULD I KNOW BEFORE I TAKE ISTURISA?

Do not use if you have ever had an allergic reaction to Isturisa 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 take Isturisa?](#) in the full CMI.

### 3. WHAT IF I AM TAKING OTHER MEDICINES?

Some medicines may interfere with Isturisa 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 TAKE ISTURISA?

The usual starting dose is two 1 mg tablets twice a day (about every 12 hours). Patients of Asian ancestry and patients with liver disease may need a lower starting dose (one 1 mg tablet twice a day).

After you have started treatment, your doctor may change your dose. This will depend on how you respond to the treatment. The highest recommended dose is 30 mg twice a day.

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

### 5. WHAT SHOULD I KNOW WHILE TAKING ISTURISA?

Things you should do	<ul style="list-style-type: none"><li>Call your doctor straight away if you have two or more of these symptoms during your treatment with Isturisa: weakness, light-headedness, tiredness, lack of appetite, nausea (feeling sick), vomiting. This may indicate that you have adrenal insufficiency (low cortisol levels)</li></ul>
Things you should not do	<ul style="list-style-type: none"><li>Do not stop using this medicine suddenly.</li></ul>
Driving or using machines	<ul style="list-style-type: none"><li>Be careful before you drive or use any machines or tools until you know how Isturisa affects you.</li><li>Isturisa may have a minor influence on the ability to drive and use machines as it has the potential to cause dizziness and fatigue. Do not drive or use machines if these symptoms occur.</li></ul>
Looking after your medicine	<ul style="list-style-type: none"><li>Store below 30°C</li><li>Store in the original package in order to protect from moisture.</li><li>Keep it where young children cannot reach it.</li></ul>

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

### 6. ARE THERE ANY SIDE EFFECTS?

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

There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur. Serious side effects are: heart disorder or heart rhythm disorder, which shows symptoms such as a fast and irregular heartbeat even when you are at rest, heart palpitations, blackouts or fainting. Adrenal insufficiency (low cortisol levels) which shows two or more symptoms of: weakness, light-headedness, tiredness, lack of appetite, nausea (feeling sick) and vomiting.

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).

# Isturisa

**Active ingredient:** Osilodrostat

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Isturisa. **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 Isturisa.**

### Where to find information in this leaflet:

1. Why am I taking Isturisa?
2. What should I know before I take Isturisa?
3. What if I am taking other medicines?
4. How do I use Isturisa?
5. What should I know while using Isturisa?
6. Are there any side effects?
7. Product details

## 1. Why am I taking Isturisa?

**Isturisa contains the active ingredient osilodrostat.**

**Isturisa is used in adults to treat endogenous Cushing's syndrome.** Cushing's syndrome is a condition in which the body produces too much of a hormone called cortisol. Too much cortisol may lead to a variety of symptoms such as weight gain (particularly around the waist), a moon-shaped face, bruising easily, irregular periods, excessive body and facial hair, and generally feeling weak, tired or unwell.

**Isturisa blocks the main enzyme that makes cortisol in the adrenal glands.** The effect of this is to decrease the over-production of cortisol and improve the symptoms of endogenous Cushing's syndrome.

## 2. What should I know before I take Isturisa?

### Warnings

#### Do not use Isturisa if:

- you are allergic to osilodrostat, 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 a heart disorder or a heart rhythm disorder, such as an irregular heartbeat, including a condition called prolonged QT syndrome (QT interval prolongation).
- if you have a liver disease; your doctor may need to change your dose of Isturisa.
- have any other medical conditions 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

This medicine should not be used during pregnancy, or breast-feeding, unless your doctor has advised you to do so.

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

### Contraception

Women who could become pregnant should use an effective method of contraception during treatment and for at least one week after the last dose. Ask your doctor about the need for contraception before you start taking Isturisa.

### Children and adolescents

This medicine is not recommended for patients aged under 18 years. This is because there is a lack of data in these patients.

## Tests before and during treatment

Your doctor will test your blood and/or urine before you start treatment and regularly during treatment. This is to detect any possible abnormalities in your magnesium, calcium and potassium levels and also to measure the levels of cortisol. Depending on the results, your doctor may change your dose.

This medicine may have an unwanted effect (called QT prolongation) on the function of the heart. Your doctor will therefore also check for this effect by performing an electrocardiogram (ECG) before you start treatment and during treatment.

If your Cushing's syndrome is caused by a benign tumour (called adenoma) in the pituitary gland, your doctor may consider stopping your treatment if a pituitary scan shows that the adenoma has expanded into neighbouring regions.

## 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.

It is particularly important that you mention any of the following medicines to your doctor or pharmacist:

- medicines that may have an unwanted effect (called QT prolongation) on the function of the heart. These include medicines used for abnormal heart rhythm such as sotalol and amiodarone; medicines used for allergies (antihistamines); antidepressants such as amitriptyline and drugs for mental health disorders (antipsychotics); antibiotics, including the following types: macrolides or fluoroquinolones; and other medicines for Cushing's disease (pasireotide)
- theophylline (used to treat breathing problems)

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

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

## 4. How do I take Isturisa?

### How much to take

The usual starting dose is two 1 mg tablets twice a day (about every 12 hours). Patients of Asian ancestry and patients with liver disease may need a lower starting dose (one 1 mg tablet twice a day).

After you have started treatment, your doctor may change your dose. This will depend on how you respond to the treatment. The highest recommended dose is 30 mg twice a day.

**Follow the instructions provided and take Isturisa until your doctor tells you to stop.**

### When to take Isturisa

Isturisa tablets are taken by mouth and can be taken with or without food.

### If you forget to take Isturisa

Isturisa should be used regularly at the same time each day. If you miss your dose at the usual time, just wait until it is time for your next dose and take that at the scheduled time.

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

**Do not stop taking Isturisa unless your doctor tells you to. If you stop your treatment with Isturisa, your symptoms may come back.**

### If you take too much Isturisa

If you think that you have taken too much Isturisa, 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 taking Isturisa?

### Things you should do

**Call your doctor straight away if you have two or more of these symptoms during your treatment with Isturisa.** This may indicate that you have adrenal insufficiency (low cortisol levels):

- weakness

- light-headedness
- tiredness
- lack of appetite
- nausea (feeling sick)
- vomiting

Remind any doctor, dentist or pharmacist you visit that you are using Isturisa.

### Things you should not do

Do not stop using this medicine suddenly.

### Driving or using machines

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

Isturisa may have a minor influence on the ability to drive and use machines as it has the potential to cause dizziness and fatigue. Do not drive or use machines if these symptoms occur.

### Looking after your medicine

Store below 30°C.

Store in original container to protect from moisture.

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

Store it in a cool dry place 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.**

### When to discard your medicine

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

### 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 throw away any medicines via wastewater or household waste. These measures will help protect the environment.

## 6. Are there any side effects?

All medicines can have side effects, although not everybody gets them. 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>Gastrointestinal disorders</b></p> <ul style="list-style-type: none"> <li>• nausea (feeling sick)</li> <li>• diarrhoea</li> <li>• abdominal pain</li> <li>• vomiting</li> </ul> <p><b>General disorders</b></p> <ul style="list-style-type: none"> <li>• tiredness (fatigue)</li> <li>• build-up of fluid leading to swelling (oedema), particularly of your ankles</li> <li>• general feeling of being unwell (malaise)</li> </ul> <p><b>Investigations</b></p> <ul style="list-style-type: none"> <li>• abnormal blood test results (increased levels of testosterone, increased levels of adrenocorticotrophic hormone, also known as ACTH, low levels of potassium) *</li> <li>• abnormal results of liver function tests *</li> </ul> <p><b>Metabolism and nutrition disorders</b></p> <ul style="list-style-type: none"> <li>• decreased appetite</li> </ul> <p><b>Nervous system disorders</b></p> <ul style="list-style-type: none"> <li>• dizziness</li> <li>• headache</li> <li>• fainting (syncope)</li> </ul> <p><b>Skin disorders</b></p> <ul style="list-style-type: none"> <li>• rash</li> <li>• excessive facial or body hair growth (hirsutism)</li> <li>• acne</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<p><b>Vascular disorders</b></p> <ul style="list-style-type: none"> <li>low blood pressure (hypotension)</li> </ul> <p><b>Cardiac disorders</b></p> <ul style="list-style-type: none"> <li>fast heartbeat (tachycardia)</li> </ul> <p>* these tests will be requested and interpreted by your doctor as part of routine monitoring (see Section 2)</p> <p><b>Musculoskeletal and connective tissue disorder</b></p> <ul style="list-style-type: none"> <li>Myalgia (muscle pain)</li> <li>Arthralgia (Joint pain)</li> </ul>	
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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.**

### Serious side effects

Serious side effects	What to do
<p><b>QT Prolongation signs:</b></p> <ul style="list-style-type: none"> <li>A heart disorder or heart rhythm disorder, such as a fast and irregular heartbeat, even when you are at rest</li> <li>heart palpitations</li> <li>blackouts or fainting</li> </ul> <p><b>Adrenal insufficiency (low cortisol levels):</b></p> <p>Tell your doctor immediately if you have <b>two or more</b> of these symptoms:</p> <ul style="list-style-type: none"> <li>weakness</li> <li>light-headedness</li> <li>tiredness (fatigue)</li> <li>lack of appetite</li> <li>nausea (feeling sick)</li> <li>vomiting.</li> </ul> <p>Adrenal insufficiency occurs when Isturisa lowers the amount of cortisol too much. It is more likely to occur during periods of increased stress. Your doctor will correct this by using a hormone medicine or by adjusting the dose of Isturisa.</p>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you 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.**

## 7. Product details

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

### What Isturisa contains

Active ingredient (main ingredient)	Osilodrostat
Other ingredients (inactive ingredients)	<p>In the tablet core:</p> <p>microcrystalline cellulose, mannitol, croscarmellose sodium, magnesium stearate, colloidal anhydrous silica.</p> <p>In the film coating:</p> <p>hypromellose, titanium dioxide (E171), iron oxides (E172, see below), macrogol and purified talc.</p> <ul style="list-style-type: none"> <li>Isturisa 1 mg film-coated tablets contain iron oxide yellow and iron oxide red.</li> <li>Isturisa 5 mg film-coated tablets contain iron oxide yellow.</li> <li>Isturisa 10 mg film-coated tablets</li> </ul>

	contain iron oxide yellow, iron oxide red and iron oxide black.
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**Do not take this medicine if you are allergic to any of these ingredients.**

### **What Isturisa looks like**

Isturisa is available in packs containing 60 film-coated tablets.

The 1 mg tablets are round, biconvex tablets with a bevelled edge, pale yellow, unscored, debossed with '1' on one side. The approximate diameter is 6.1 mm.

The 5 mg tablets are round, biconvex tablets with a bevelled edge, yellow, unscored, debossed with '5' on one side. The approximate diameter is 7.1 mm.

The 10 mg tablets are round, biconvex tablets with a bevelled edge, pale orange brown, unscored, debossed with '10' on one side. The approximate diameter is 9.1 mm (Aust R 369220, 369219 , 369218 ).

### **Who distributes Isturisa**

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