

## 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 ZIRDAWNY?

ZIRDAWNY contains the active ingredient donidalorsen. ZIRDAWNY is used to prevent angioedema attacks in patients with hereditary angioedema (HAE) aged 12 years and older.

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

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

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

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

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

For more information, See Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use ZIRDAWNY?

- The recommended dose is 1 injection a month under the skin (subcutaneously) administered with 1 pre-filled pen.
- If you have not had an attack for a long period, your doctor may change the dose to 1 injection every 2 months.
- If you inject ZIRDAWNY yourself or if your caregiver injects it, you or your caregiver must carefully read and follow the detailed instructions in the "Instructions for use" found in the ZIRDAWNY carton.

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

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

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using ZIRDAWNY.</li><li>• Call your doctor straight away or go to the Emergency Department at your nearest hospital if you have a severe allergic reaction to ZIRDAWNY with symptoms such as hives, tight chest, low blood pressure (such as feeling dizzy or light-headed), or signs of anaphylaxis such as difficulty breathing or wheezing.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine suddenly.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• ZIRDAWNY has no or negligible influence on the ability to drive and use machines.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store in a refrigerator (2°C to 8°C).</li><li>• Do not freeze.</li><li>• Do not expose to heat.</li><li>• Keep the pre-filled pen in the outer carton in order to protect from light.</li></ul>

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

### 6. Are there any side effects?

Common side effects include injection site reactions (such as change in skin colour, redness, pain, and itching) and abnormal liver blood test results. A serious side effect is severe allergic reactions, including rash, difficulties in breathing, tight chest, wheezing, swelling around your mouth, and fast heart beat.

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).

# ZIRDAWNY®

Active ingredient(s): donidalorsen

## Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

## 1. Why am I using ZIRDAWNY?

ZIRDAWNY contains the active ingredient donidalorsen.

ZIRDAWNY is a type of medicine called an antisense oligonucleotide inhibitor. Donidalorsen blocks the activity of plasma kallikrein, which helps to reduce the amount of bradykinin in the bloodstream and prevents symptoms of hereditary angioedema (HAE).

**ZIRDAWNY is used to prevent angioedema attacks in patients with HAE aged 12 years and older.**

HAE is a condition which runs in families. With this condition your blood does not have enough of a protein called C1 inhibitor, or the C1 inhibitor does not work properly. This leads to too much plasma kallikrein, which in turn produces higher levels of bradykinin in your bloodstream. Too much bradykinin leads to symptoms of HAE like swelling and pain in different parts of your body including:

- hands and feet
- face, eyelids, lips or tongue
- voice-box (larynx), which may make breathing difficult
- genitals
- stomach and intestines

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

### Warnings

**Do not use ZIRDAWNY if:**

- you are allergic to donidalorsen, 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 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

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.

There is limited information on the safety of use of ZIRDAWNY during pregnancy and breast-feeding. As a precautionary measure, it is preferable to avoid the use of ZIRDAWNY during pregnancy.

This medicine may pass into breast milk and it is not known if this medicine can affect your baby. Your doctor will discuss with you whether to stop treatment with this medicine while you are breast-feeding, or to stop breast-feeding.

Your doctor will discuss with you the risks and benefits of taking this medicine.

### Children and adolescents

- ZIRDAWNY is not recommended in children under 12 years. This is because it has not been studied in this age group.

### ZIRDAWNY contains sodium

- This medicine contains less than 1 mmol sodium (23 mg) per pre-filled pen.

## 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.

ZIRDAWNY is not known to affect other medicines or be affected by other medicines.

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

## 4. How do I use ZIRDAWNY?

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

ZIRDAWNY is provided in single-use pre-filled pens as ready-to-use solution for injection. Product is for single use in one patient only. Discard any residue. Your treatment will be started and managed under the supervision of a doctor experienced in the care of patients with HAE.

### How much to use

- The recommended dose is one injection a month under the skin (subcutaneously) administered with 1 pre-filled pen.
- If you have not had an attack for a long period, your doctor may change the dose to one injection every two months.
- Follow the instructions provided and use ZIRDAWNY until your doctor tells you to stop.

### How to inject ZIRDAWNY

If you inject ZIRDAWNY yourself or if your caregiver injects it, you or your caregiver must carefully read and follow the detailed instructions in the "Instructions for Use" found in the ZIRDAWNY carton.

- ZIRDAWNY is for injection under the skin (subcutaneous injection).
- The injection can be given either by yourself or a caregiver.
- A doctor, pharmacist or nurse should show you how to prepare and inject ZIRDAWNY properly before you use it for the first time. Do not inject yourself or someone else until you have been trained to inject the medicine.
- Insert the needle into the fatty tissue in the tummy (abdomen), the front of the thigh or the back of the upper arm.
- Injections in the back of the upper arm must only be given by caregivers.
- Change your injection site with each monthly injection
- Use each pre-filled pen of ZIRDAWNY only once.

### If you forget to use ZIRDAWNY

ZIRDAWNY should be used regularly at the same time each month or every two months, as indicated by your doctor. If you miss your dose at the usual time, inject the missed dose as soon as you remember. Thereafter resume dosing at the prescribed dosing frequency (once monthly or once every two months), as instructed by your doctor, from the date of the most recently administered dose.

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

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

### If you use too much ZIRDAWNY

If you think that you have used too much ZIRDAWNY, 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 ZIRDAWNY?

### Things you should do

**Call your doctor straight away or go to the nearest hospital if you:**

- have a severe allergic reaction to ZIRDAWNY with symptoms such as hives, tight chest, low blood pressure (such as feeling dizzy or light-headed), or signs of anaphylaxis such as difficulty breathing or wheezing.

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

### Things you should not do

- Do not stop using this medicine suddenly.

### Driving or using machines

ZIRDAWNY has no or negligible influence on the ability to drive and use machines.

### Looking after your medicine

- Store in a refrigerator (2°C to 8°C).
- Do not freeze.
- Do not expose to heat.
- Keep the pre-filled pen in the outer carton in order to protect from light.

ZIRDAWNY may be stored in the original carton unrefrigerated for up to 6 weeks below 30°C. If not used within 6 weeks, it should be discarded.

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

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

Do not use this medicine if you notice the following:

- clear cap is missing or not attached.
- expiry date has passed.
- medicine looks cloudy, discoloured, or has particles.
- pre-filled pen appears damaged.

Do not use this medicine after the expiry date which is stated on the label and carton 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.

## 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
<ul style="list-style-type: none"><li>• Injection site reactions such as change in skin colour, redness, pain, itching, hardening, haematoma (bleeding under the skin at the site of the injection), bruising, scaling of the skin, allergic reaction or swelling.</li><li>• Blood tests showing liver changes.</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>• Severe allergic reactions. Symptoms include:<ul style="list-style-type: none"><li>o rash</li><li>o difficulties in breathing</li><li>o tight chest</li><li>o wheezing</li><li>o swelling around your mouth</li><li>o fast heart beat</li></ul></li></ul>	<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>

**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 ZIRDAWNY contains

<b>Active ingredient (main ingredient)</b>	Each pre-filled pen contains 80 mg of donidalorsen in 0.8 mL of solution.
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• Monobasic sodium phosphate dihydrate</li><li>• Dibasic sodium phosphate</li><li>• Sodium chloride</li><li>• Water for injections</li><li>• Hydrochloric acid</li><li>• Sodium hydroxide</li></ul>

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

### What ZIRDAWNY looks like

ZIRDAWNY is a clear, colourless to yellow solution for injection in a pre-filled pen.

ZIRDAWNY is available as a single pack containing 1 pre-filled pen in a carton and a single pack containing 3 pre-filled pens in a carton.

1 x single-use pre-filled pen (AUST R 490867).

3 x single-use pre-filled pens (AUST R 490867).

### Who distributes ZIRDAWNY

Otsuka Australia Pharmaceutical Pty Ltd

Suite 2.03, Level 2

9 Help Street

Chatswood NSW 2067

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