

# SKYCLARYS™

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## 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.

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

## 1. Why am I using SKYCLARYS?

SKYCLARYS contains the active ingredient omaveloxolone. SKYCLARYS is used for the treatment of Friedreich's ataxia in adults and adolescents 16 years and older.

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

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

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

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

Some medicines may interfere with SKYCLARYS 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 SKYCLARYS?**

- A physician will supervise your treatment with SKYCLARYS.
- The recommended dose is 150#mg omaveloxolone (3 capsules) taken orally once daily.

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

### **5. What should I know while using SKYCLARYS?**

<b>Things you should do</b>	
	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist</li></ul>

you visit that you are using SKYCLARYS.

- Your doctor will check to see how well your liver is working, your cholesterol level and your level of BNP (B-type natriuretic peptide, a blood test that is a marker of heart problems) before you start taking SKYCLARYS.
- Your doctor will be checking blood tests while you are taking SKYCLARYS.
- Contact your doctor immediately if you have sudden weight gain, swelling of legs, ankles, or feet, or shortness of breath, which may be signs or symptoms of heart problems while taking SKYCLARYS.
- SKYCLARYS can reduce the effectiveness of hormonal birth control. You should use a different method of birth control and tell your

	<p>doctor immediately if you become pregnant.</p>
<p><b>Things you should not do</b></p>	<ul style="list-style-type: none"> <li>• Do not stop using this medicine unless your doctor has told you to.</li> <li>• Avoid eating grapefruit or grapefruit juice while taking SKYCLARYS.</li> </ul>
<p><b>Driving or using machines</b></p>	<ul style="list-style-type: none"> <li>• Be careful before you drive or use any machines or tools until you know how SKYCLARYS affects you.</li> <li>• Some people may feel tired after taking this medicine. If you feel tired after taking SKYCLARYS, avoid driving and using machines.</li> </ul>
<p><b>Looking after your medicine</b></p>	<ul style="list-style-type: none"> <li>• Store below 30°C.</li> <li>• If the capsule is opened and mixed with apple sauce you must eat all the apple sauce/ medicine mixture immediately after making it.</li> </ul>

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

## **6. Are there any side effects?**

Very common side effects include digestive problems such as nausea, diarrhoea, vomiting, stomach pain and decrease in weight.

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).

## SKYCLARYS™

**Active ingredient:** *omaveloxolone*

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### Consumer Medicine Information (CMI)

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

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

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

## 1. Why am I using SKYCLARYS?

**SKYCLARYS contains the active ingredient omaveloxolone**, which activates a specific protein, Nrf2, in your body.

The protein called Nrf2 in your body has a key role in managing oxidative stress (a condition that can damage cells in your body) and has a protective role against neurodegenerative diseases. In people with Friedreich's ataxia, Nrf2 activity is reduced. SKYCLARYS activates Nrf2 so it can manage oxidative stress.

**SKYCLARYS is indicated for the treatment of Friedreich's ataxia in adults and adolescents aged 16 years and older.**

Friedreich's ataxia is a rare inherited disease that causes progressive damage to your nervous system and movement problems.

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

### Warnings

#### **Do not use SKYCLARYS if:**

- you are allergic to omaveloxolone, 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
- have problems with your liver, your doctor may decide to change the dose or not start treatment with SKYCLARYS.

Your doctor will check to see how well your liver is working and will check your cholesterol level before you start taking SKYCLARYS. Your doctor will also check your level of BNP (B-type natriuretic peptide, a blood test that is a marker of heart problems) before you start taking SKYCLARYS.

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.

You should not take SKYCLARYS if you are pregnant, think you may be pregnant, or are planning to have a baby. Tell your doctor immediately if you become pregnant while you are being treated with SKYCLARYS.

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



Do not breast-feed your baby while you are being treated with SKYCLARYS. It is not known if this medicine passes into the breast milk.

Using SKYCLARYS can reduce the effectiveness of hormonal birth control. You should use a different method of birth control, such as a non-hormonal IUD (intrauterine device). A reliable method of birth control should be used during SKYCLARYS treatment and for 28 days after stopping treatment with SKYCLARYS. Talk to your doctor about the most suitable birth control for you.

## **Children and adolescents**

Do not give SKYCLARYS to children and adolescents below the age of 16 years because it has not yet been studied in this population.

### **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 may interfere with SKYCLARYS and affect how it works.**

Certain medicines may increase the risk of side effects of SKYCLARYS by increasing the levels of SKYCLARYS in the blood.

**Medicines that may increase the effect of SKYCLARYS include:**

- itraconazole, fluconazole, or ketoconazole (antifungal medicines used to treat a number of fungal infections)
- cyclosporine (a medicine used after organ transplant)
- ciprofloxacin or clarithromycin (antibiotics used for bacterial infections)
- fluvoxamine (an antidepressant known as a selective serotonin reuptake inhibitor [SSRI])

Certain medicines may reduce how well SKYCLARYS works by decreasing the amount of SKYCLARYS in the blood.

**Medicines that may reduce the effect of SKYCLARYS include:**

- St. John's wort (a herbal remedy used for mild depression)
- rifampicin (used to treat tuberculosis)
- carbamazepine, phenobarbital, phenytoin, primidone (used to treat epilepsy)
- efavirenz (medicine used for HIV)

SKYCLARYS may reduce how well some other medicines work by decreasing the amount of these medicines in the blood.

**SKYCLARYS may reduce the effect of these other medicines:**

- midazolam (used as a sedative and to treat severe agitation)
- repaglinide (a medicine to control type II diabetes)

- rosuvastatin (a statin medicine used to reduce harmful lipids)
- hormonal contraceptives (a type of birth control that uses hormones to prevent pregnancy, such as the pill, patch, or ring)

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

## **4. How do I use SKYCLARYS?**

### **How much to take**

- The recommended dose is 150 mg (3 capsules) taken orally once daily.
- Follow the instructions provided and use SKYCLARYS until your doctor tells you to stop.

### **When to take SKYCLARYS**

- SKYCLARYS capsules should be swallowed whole.
- For people who are unable to swallow whole capsules, SKYCLARYS capsules may be opened, and the entire contents sprinkled onto 2 tablespoons of apple sauce.
- You should consume all the medicine/food mixture immediately on an empty stomach at least 1 hour before or 2 hours after eating.

## **If you forget to take SKYCLARYS**

SKYCLARYS should be used regularly at the same time each day.

**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 SKYCLARYS**

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

**You should immediately:**

- **phone the Poisons Information Centre (by calling 13 11 26 in Australia or 0800 764 766 in New Zealand), 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 SKYCLARYS?**

### **Things you should do**

#### **Call your doctor straight away if you:**

- Contact your doctor immediately if you have sudden weight gain, swelling of legs, ankles, or feet, or shortness of breath, which may be signs or symptoms of heart problems while taking SKYCLARYS.
- Tell your doctor immediately if you become pregnant while you are being treated with SKYCLARYS.

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

### **Things you should not do**

- Do not stop using this medicine unless your doctor has told you to.
- Avoid eating grapefruit or grapefruit juice while taking SKYCLARYS.

### **Talk to your doctor**

- Your doctor will be checking blood tests while you are taking SKYCLARYS. This will include liver blood tests to see how your liver is working while taking SKYCLARYS.
- Based on your blood tests, your doctor may tell you that you have high liver enzymes. Your doctor will

decide on whether to discontinue SKYCLARYS if liver problems develop.

- Based on your blood tests, your doctor may tell you that you have increased BNP (a marker of heart problems). Your doctor will decide on treatment and whether SKYCLARYS should be continued.
- Based on your blood tests, your doctor may tell you that you have changes in your blood cholesterol and triglycerides.
- Tell your doctor if you have weight loss with SKYCLARYS.

## **Driving or using machines**

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

Some people may feel tired after taking this medicine. If you feel tired after taking SKYCLARYS, avoid driving and using machines.

## **Looking after your medicine**

- Store below 30°C.

Follow the instructions on 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.**

## 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
<ul style="list-style-type: none"><li>• headache</li><li>• tiredness</li><li>• sore throat</li><li>• back pain</li><li>• muscle spasm</li><li>• flu</li><li>• decreased appetite</li><li>• urinary tract infection (UTI)</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• period pains in women (menstrual cramps)</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<b>Digestive problems:</b> <ul style="list-style-type: none"> <li>• nausea</li> <li>• diarrhoea</li> <li>• vomiting</li> <li>• stomach pain</li> <li>• decrease in weight</li> </ul>	<b>Talk to your doctor immediately if you have any of these 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 SKYCLARYS contains**

<b>Active ingredient (main ingredient)</b>	50 mg omaveloxolone
<b>Other ingredients (inactive ingredients)</b>	Capsule contents: pregelatinised maize starch croscarmellose sodium magnesium stearate silicified microcrystalline cellulose Capsule shell: hypromellose titanium dioxide brilliant blue FCF iron oxide yellow

	opacode white A-8154NB (ID 2620) printing ink
<b>Potential allergens</b>	none

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

## **What SKYCLARYS looks like**

SKYCLARYS capsules are opaque with “RTA 408” printed on the light green body in white ink and “50” printed on the blue cap in white ink.

SKYCLARYS capsules are supplied as:

Pack size of 90 capsules (AUST R 453725)

Pack size of 270 (3 packs of 90) capsules (AUST R 453725)\*

\* not all pack sizes are marketed

## **Further information**

You can obtain more information from your doctor or pharmacist or by telephoning 1800 852 289 in Australia or 0800 852 289 in NZ

## **Who distributes SKYCLARYS**

SKYCLARYS is supplied in Australia by:

Biogen Australia Pty Ltd

ABN 30 095 760 115

Level 4, 2 Banfield Road

Macquarie Park NSW 2113

SKYCLARYS is supplied in New Zealand by:

Biogen NZ Biopharma Limited

Auckland, New Zealand

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