Givlaari®

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. Read before using this medicine.

1. Why am I using Givlaari?

Givlaari contains the active ingredient givosiran. Givlaari is used to treat acute hepatic porphyria in adults and adolescents aged 12 years and older.

For more information, see Section 1. Why am I using Givlaari? in the full CMI.

2. What should I know before I use Givlaari?

Do not use if you have ever had an allergic reaction to givosiran 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 Givlaari? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Givlaari 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 is Givlaari given?

- This medicine will be given to you once every month by a doctor or nurse.
- It is given as an injection under the skin (subcutaneously) into your stomach area (abdomen), or in some cases, your upper arm or thigh.

More instructions can be found in Section 4. How is Givlaari given? in the full CMI.

5. What should I know while using Givlaari?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Givlaari. • Tell your doctor if you are pregnant or breastfeeding or are planning to become pregnant.
Things you should not do	• Do not stop treatment with Givlaari unless your doctor tells you to.
Driving or using machines	• This medicine is unlikely to have any effect on your ability to drive or use machines.
Looking after your medicine	• 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 vial after EXP. The expiry date refers to the last day of that month. • This medicine is for single use only. Once the product is opened, use immediately. • Store below 25 °C

For more information, see Section 5. What should I know while using Givlaari? in the full CMI.

6. Are there any side effects?

Tell your doctor or nurse straight away if you get any of the following signs of a severe allergic reaction (anaphylactic reaction): swelling of the lips, tongue or throat, breathing problems or wheezing, feeling dizzy or fainting, and/or rash, hives and itching.

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.

Givlaari®

Active ingredient(s): *givosiran*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using Givlaari?

Givlaari contains the active ingredient givosiran.

Givlaari is used to treat acute hepatic porphyria in adults and adolescents aged 12 years and older.

Acute hepatic porphyria is a rare illness that runs in families. It is caused by a defect in one of the proteins that make a molecule called haem in the liver. Because there is a problem in one of the proteins required to make haem, there is a build-up of some of the substances that are used to produce haem, namely aminolevulinic acid (ALA) and porphobilinogen (PBG). Having too much ALA and PBG can injure nerves and cause serious attacks of pain, nausea, muscle weakness and changes in mental functioning. Some people with acute hepatic porphyria may also have symptoms, such as pain and nausea, in between attacks. Longer-term complications that can be seen in people with acute hepatic porphyria include high blood pressure, chronic kidney disease and liver disease.

Givlaari works by lowering the amount of an enzyme, called ALAS1, that controls how much ALA and PBG are made by the liver. By lowering ALAS1, the liver makes less ALA and PBG. This can help to reduce the effects of this illness.

2. What should I know before I use Givlaari?

Warnings

Do not use Givlaari if:

- You are allergic to givosiran, 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?

Severe allergic reaction

- Tell your doctor or nurse straight away if you get any signs of a severe allergic reaction. The signs are listed in “Serious side effects” in section 4.
- If you have a severe allergic reaction, your doctor or nurse will stop using the medicine straight away and you may need to take other medicines to control the symptoms.

Liver problems

- Using this medicine can affect your liver. You will have blood tests to check your liver function before you start treatment with Givlaari and periodically during treatment. If these tests show abnormal results, your doctor or nurse will decide whether to interrupt treatment or stop treatment permanently. Abnormal results have been seen in some patients treated with this medicine, mainly between 3 to 5 months after starting treatment.

Kidney problems

- Using this medicine can affect your kidneys, especially if you have already been diagnosed with kidney problems. Your doctor will check how your kidneys are working while you are using this medicine, especially if you already have kidney problems.

Tests for homocysteine levels

- While receiving this medicine, blood tests may show an increase in homocysteine, a type of amino acid, compared to your homocysteine levels before starting treatment. Your doctor will check the levels of homocysteine in your blood before and during treatment. If your homocysteine levels are elevated, your doctor may recommend taking a supplement with vitamin B6.

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.

Studies in animals suggest this medicine may pass into breast milk. If you are breast-feeding ask your doctor for advice before taking this medicine. Your doctor will then help you decide whether to stop breast-feeding or to stop treatment with Givlaari taking into account the benefit of breast-feeding for your child and benefit of therapy for you.

Use in children and adolescents

- This medicine should not be used in children below 12 years of age because there is no experience of using the medicine in this age group.

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 Givlaari and affect how it works.

When using certain medicines, this medicine may prolong or increase their effect or change their side effects.

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

4. How is Givlaari given?

How much Givlaari is given?

- Your doctor will work out how much medicine to give you. The amount will depend on your body weight.
- The recommended dose is 2.5 milligrams for every kilogram you weigh.
- You will be given the medicine once a month (every 4 weeks).
- If blood tests show problems with your liver, your doctor may interrupt Givlaari treatment or stop treatment permanently. Your doctor may consider starting again at a lower dose.

How Givlaari is given

- Givlaari will be given to you once every month by a doctor or nurse. It is given as an injection under the skin (subcutaneously) into your stomach area (abdomen), or in some cases, your upper arm or thigh. The site of the injection will be rotated. If the dose is more than 1 mL, more than one vial will need to be used and more than one subcutaneous injection may need to be given.

If you miss your dose of Givlaari

- If you have missed an appointment for your injection, talk to your doctor or nurse as soon as possible.
- If you have any further questions on the use of this medicine, ask your doctor or nurse.

If you are given too much Givlaari

This medicine will be given to you by your doctor or nurse. In the unlikely event that you are given too much (an overdose) your doctor or nurse will check you for side effects.

In the unlikely event you are not with a healthcare professional, 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 Givlaari?

Things you should do

Tell your doctor if you are planning to become pregnant.

Call your doctor straight away if you:

- If you get any signs of a severe allergic reaction. The signs are listed in “Serious side effects” in section 6.
- If you have a severe allergic reaction, your doctor or nurse will stop using the medicine straight away and you may need to take other medicines to control the symptoms.

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

Things you should not do

Your doctor will tell you how long you need to receive Givlaari. Do not stop treatment with Givlaari unless your doctor tells you to.

Driving or using machines

Givlaari is unlikely to have any effect on your ability to drive or use machines.

Looking after your medicine

- Do not use this medicine after the expiry date which is stated on the carton and vial after EXP. The expiry date refers to the last day of that month.
- This medicine is for single use only. Once the product is opened, use immediately.
- Store below 25 °C.
- Keep vial in the outer carton to protect from light.

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

Keep this medicine where young children cannot reach it.

Getting rid of any unwanted medicine

Do not throw away any medicines via wastewater or household waste. Your doctor or nurse will throw away any medicines that are no longer being used. These measures will help protect the environment.

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.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Givlaari.

Less serious side effects

Less serious side effects	What to do
Gastrointestinal disorders: • Nausea **General disorders and administration site conditions:** • Redness, pain, itching or swelling at the site of the injection (injection site reaction) • Feeling tired **Skin disorders:** • Skin rashes including red, itchy or dry skin, eczema or hives	**Speak to your doctor if you have any of these less serious side effects.**

Serious side effects

Serious side effects	What to do
Severe allergic reactions: • swelling – mainly of the lips, tongue or throat which makes it difficult to swallow or breathe • breathing problems or wheezing • feeling dizzy or fainting • rash, hives • itching **Liver disorders:** • Blood tests showing an increase in transaminases, which are liver enzymes (a sign of possible liver inflammation)* **Kidney disorders:** • Blood tests showing an increase in creatinine, a substance removed from your body by your kidneys, or decrease in glomerular filtration rate (signs of possible kidney problems)* **Investigations** • Blood test showing an increase in homocysteine (a type of amino acid)* * These tests will be requested and interpreted by your doctor as part of routine monitoring (see What should I know before I use Givlaari?)	**Call your doctor or nurse straight away if you notice any of these serious side effects.** **Your doctor or nurse will receive the test results and may advise you to modify or stop taking the medicine**

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. 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 Givlaari contains

Active ingredient (main ingredient)	Givosiran
Other ingredients (inactive ingredients)	Sodium hydroxide Phosphoric acid Water for injections
Potential allergens	N/A

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

What Givlaari looks like

Givlaari is a clear, colourless to yellow solution for injection.

Each pack contains one vial of 1 mL solution for injection.

Aust R 401153.

Who distributes Givlaari

Medison Pharma Australia Pty Ltd
1 Bligh Street
Sydney NSW 2000
Australia

Phone: 1800 566 020

Email: MedInfo.Australia@Medisonpharma.com

www.medisonpharma.com.au

This leaflet was prepared in July 2024.