

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 Onpattro?

Onpattro contains the active ingredient patisiran. Onpattro is used to treat an illness which runs in families called hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis).

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

2. What should I know before I use Onpattro?

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

3. What if I am taking other medicines?

Some medicines may interfere with Onpattro 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 Onpattro?

- The usual dose of Onpattro is 300 micrograms per kilogram (kg) of body weight given once every 3 weeks.
- Onpattro will be given to you by a doctor or nurse. It is given as a drip into a vein ('intravenous infusion') usually over about 80 minutes.

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

5. What should I know while using Onpattro?

| | |
|------------------------------------|--|
| Things you should do | <ul style="list-style-type: none">• Tell your doctor if you are pregnant or breastfeeding, or are planning to become pregnant• Remind any doctor, dentist, or pharmacist you visit that you are using Onpattro. |
| Things you should not do | <ul style="list-style-type: none">• Your doctor will tell you how long you need to receive Onpattro. Do not stop treatment with Onpattro unless your doctor tells you to. |
| Driving or using machines | <ul style="list-style-type: none">• Onpattro is believed to have no or negligible influence on the ability to drive or use machines. Your doctor will tell you whether your condition allows you to drive vehicles and use machines safely. |
| Looking after your medicine | <ul style="list-style-type: none">• Keep this medicine where young children cannot reach it.• Do not use this medicine after the expiry date which is stated on the carton after 'EXP'. The expiry date refers to the last day of that month.• Store in a refrigerator (2°C to 8°C). Do not freeze.• If refrigeration is not available, Onpattro can be stored at room temperature (up to 25°C) for up to 14 days. Onpattro must be discarded if not used within the 14 day period. |

For more information, see Section [5. What should I know while using Onpattro?](#) 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 an infusion-related reaction during treatment. The infusion may need to be slowed down or stopped, and you may need to take other medicines to manage the reaction.

You may experience stomach pain, feeling sick (nausea), body aches or pain, headache, feeling tired, chills, dizziness, cough, hoarseness, feeling short of breath or other breathing problems, reddening of the face or body (flushing), warm skin, rash or itching, chest discomfort or chest pain, rapid heart rate or low or high blood pressure (some patients have fainted during the infusion due to low blood pressure), pain, redness, burning sensation, or swelling at or near the infusion site or swelling of the face.

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.

Onpattro[®]

Active ingredient(s): *patisiran*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using Onpattro?

Onpattro contains the active ingredient *patisiran*.

This medicine is used to treat an illness which runs in families called **hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis)**.

- hATTR amyloidosis is caused by problems with a protein in the body called ‘transthyretin’ (TTR).
- This protein is made mostly in the liver and carries vitamin A and other substances around the body.
- In people with this illness, abnormally shaped TTR proteins clump together to make deposits called ‘amyloid’.
- Amyloid can build up around the nerves, heart, and other places in the body, preventing them from working normally. This causes the symptoms of the illness.

Onpattro works by lowering the amount of TTR protein that the liver makes.

- This means there is less TTR protein in the blood that can form amyloid.
- This can help to reduce the effects of this illness.

Onpattro is used in adults only.

2. What should I know before I use Onpattro?

Warnings

Do not use Onpattro if:

- you are allergic to *patisiran*, 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?](#)

Infusion-related reactions

Onpattro is given as a drip into a vein (called an ‘intravenous infusion’). Reactions to this infusion may happen during treatment with Onpattro. Before each infusion you will be given medicines that help to lower the chance of infusion related reactions (see ‘How Onpattro is given’ in section 4).

Tell your doctor or nurse straight away if you get any signs of an infusion-related reaction. These signs are listed in section 6.

If you have an infusion-related reaction, your doctor or nurse may slow down or stop your infusion, and you may need to take other medicines to control the symptoms. When these reactions stop, or get better, your doctor or nurse may decide to start the infusion again.

Vitamin A deficiency

Treatment with Onpattro lowers the amount of vitamin A in your blood. Your doctor will measure your vitamin A levels, and if they are too low they should have returned to normal and any symptoms due to vitamin A deficiency should have resolved before you start treatment with Onpattro. Symptoms of vitamin A deficiency may include:

- Decrease in night vision, dry eyes, poor vision, hazy or cloudy vision

If you have problems with your vision or any other eye problems whilst using Onpattro, you should talk to your doctor. Your doctor may refer you to an eye specialist for a check-up if it is necessary.

Your doctor will ask you to take a daily vitamin A supplement during treatment with Onpattro.

Both too high and too low levels of vitamin A can harm the development of your unborn child. Therefore, women of childbearing age should not be pregnant when starting treatment with Onpattro and should practise effective

contraception (see section “Pregnancy and breastfeeding” below).

Pregnancy and breastfeeding

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

You should not use Onpattro if you are pregnant, unless advised by your doctor.

Onpattro will reduce the level of vitamin A in your blood, which is important for normal development of your unborn child. If you are a woman of child-bearing age, you should practise effective contraception during treatment with Onpattro. Talk to your doctor or nurse about suitable methods of contraception. Pregnancy should be excluded before starting treatment with Onpattro.

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

Ingredients of Onpattro may pass into breast milk. Talk to your doctor about stopping breast-feeding or treatment with Onpattro.

Use in children and adolescents

Onpattro is not recommended in children and adolescents under 18 years of age.

Onpattro contains sodium

This medicine contains 3.99 milligrams (mg) of sodium (main component of cooking/table salt) per millilitre (mL). This is 0.2% of the recommended maximum daily dietary intake of sodium for an adult.

3. What if I am taking other medicines?

Tell your doctor, nurse 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 important to tell your doctor, nurse or pharmacist if you are taking any of the following medicines as your doctor may need to change the dose:

- Bupropion, a medicine used to treat depression or to help you to stop smoking
- Efavirenz, a medicine used to treat HIV infection and AIDS

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

4. How Onpattro is given

How much to give

- Your doctor will work out how much Onpattro to give you - this will depend on your body weight.
- The usual dose of Onpattro is 300 micrograms per kilogram (kg) of body weight given once every 3 weeks.

How Onpattro is given

- Onpattro will be given to you by a doctor or nurse.
- It is given as a drip into a vein (‘intravenous infusion’) usually over about 80 minutes.

If you do not have problems with your infusions in the clinic, your doctor may talk with you about a healthcare professional giving you your infusions at home.

Medicines given during treatment with Onpattro

Before each infusion of Onpattro, you will be given medicines that help to lower the risk of infusion-related reactions. These include antihistamines, a corticosteroid (a medicine that suppresses inflammation), and a pain reliever.

How long to use Onpattro

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

If you miss your dose of Onpattro

If you miss an appointment to have Onpattro, ask your doctor or nurse when to book your next treatment.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

If you are given too much Onpattro

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 that 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 Onpattro?

Things you should do

If you have problems with your vision or any other eye problems whilst using Onpattro, you should talk to your doctor. Your doctor may refer you to an eye specialist for a check-up if it is necessary.

If you are a woman of child-bearing age, you should practise effective contraception during treatment with Onpattro.

Tell your doctor if you are planning to become pregnant. Your doctor may tell you to stop taking Onpattro. Your

doctor will ensure that your vitamin A levels have returned to normal before you try to become pregnant.

Call your doctor straight away if you:

- **get any signs of an infusion-related reaction.** These signs are listed in section [6 Are there any side effects](#) > Infusion related reactions.
- **if you have an unplanned pregnancy.** Your doctor may tell you to stop taking Onpattro. During the first 3 months of your pregnancy, your doctor may tell you to stop your vitamin A supplement. During the last 6 months of your pregnancy, you should resume vitamin A supplementation if the vitamin A levels in your blood have not yet returned to normal, because of an increased risk of vitamin A deficiency during the last 3 months of your pregnancy.

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

Things you should not do

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

Driving or using machines

Onpattro is believed to have no or negligible influence on the ability to drive or use machines. Your doctor will tell you whether your condition allows you to drive vehicles and use machines safely.

Looking after your medicine

- Do not use this medicine after the expiry date which is stated on the carton after 'EXP'. The expiry date refers to the last day of that month.
- Store in a refrigerator (2°C to 8°C). Do not freeze.
- If refrigeration is not available, Onpattro can be stored at room temperature (up to 25°C) for up to 14 days. Onpattro must be discarded if not used within the 14 day period.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

Medicines should not be disposed of via wastewater or household waste. Your healthcare professional 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, nurse, or pharmacist if you have any further questions about side effects.

Less serious side effects

| Less serious side effects | What to do |
|--|---|
| <p>Other side effects:</p> <ul style="list-style-type: none"> • Muscle spasms • Indigestion (dyspepsia) • Feel like the room is spinning (vertigo) • Irritation or infection of the airways (sinusitis, bronchitis) • Redness of the skin (erythema) • Pain in the joints (arthralgia) • Stuffy or runny nose (rhinitis) | <p>Speak to your doctor or nurse if you have any of these less serious side effects.</p> |

Serious side effects

| Serious side effects | What to do |
|--|--|
| <ul style="list-style-type: none"> • Infusion-related reactions: <ul style="list-style-type: none"> • Cough, feeling short of breath, or other breathing problems • Changes to the sound or tone of your voice (hoarseness) • Reddening of the face or body (flushing), warm skin, rash or itching • Chest discomfort or chest pain • Rapid heart rate • Low or high blood pressure; some patients have fainted during the infusion due to low blood pressure • Pain, redness, burning sensation, or swelling at or near the infusion site • Swelling of the face • Stomach pain • Feeling sick (nausea) • Body aches or pain, including pain in the back, neck, or joints • Headache • Feeling tired (fatigue) • Chills • Dizziness • Swelling of the arms or legs (peripheral oedema) • Shortness of breath (dyspnoea) • Leakage of the drug into the surrounding tissue at the site of infusion, which may cause swelling or redness (extravasation) | <p>Tell your doctor or nurse straight away if you notice any of these serious side effects.</p> |

Tell your doctor, nurse 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 Onpattro contains

| | |
|---|---|
| Active ingredient (main ingredient) | Patisiran |
| Other ingredients (inactive ingredients) | <ul style="list-style-type: none">• DLin-MC3-DMA ((6Z,9Z,28Z,31Z)-heptatriaconta-6,9,28,31-tetraen-19-yl-4-(dimethylamino) butanoate)• PEG₂₀₀₀-C-DMG (1,2-Dimyristoyl-sn-glycero-3-carboxaminopropylpolyethylene glycol 2000 methyl ether)• Distearoylphosphatidylcholine [DSPC (1,2-distearoyl-sn-glycero-3-phosphocholine)]• Cholesterol• Dibasic sodium phosphate heptahydrate• Monobasic potassium phosphate• Sodium chloride• Water for injections |
| Potential allergens | N/A |

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

What Onpattro looks like

Onpattro is presented in vials containing patisiran sodium equivalent to 10 mg patisiran. Each mL contains patisiran sodium equivalent to 2 mg patisiran.

Onpattro is a white to off-white, opalescent, homogeneous concentrated injection for infusion.

Aust R 380813.

Who sponsors Onpattro

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