

ORFADIN® Capsules

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.

1. Why am I using ORFADIN?

ORFADIN contains the active ingredient nitisinone. ORFADIN is used for the treatment of a disease called hereditary tyrosinaemia type 1 (HT-1). For more information, see Section [1. Why am I using ORFADIN?](#) in the full CMI.

2. What should I know before I use ORFADIN?

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

3. What if I am taking other medicines?

Some medicines may interfere with ORFADIN 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 ORFADIN?

- Take ORFADIN with food. Swallow the capsule whole with a full glass of water.
- Your doctor will prescribe the correct dose for you. Your doctor will adjust your ORFADIN dose based on your response to ORFADIN and your test results.

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

5. What should I know while using ORFADIN?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using ORFADIN.• It is very important that you stay on the special diet, with low tyrosine and phenylalanine content that your doctor recommended.
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	<ul style="list-style-type: none"> • Tell your doctor if you are pregnant or breastfeeding, or intend to become pregnant or breastfeed. • Tell your doctor immediately if you experience red eyes, clouding or inflammation of the eyes, inflammation of the eyelid, sensitivity to light, or eye pain.
Things you should not do	<ul style="list-style-type: none"> • Do not stop using this medicine or lower the dosage without checking with your doctor. • Do not breastfeed while taking ORFADIN
Driving or using machines	<ul style="list-style-type: none"> • Be careful driving or operating machinery or doing other jobs until you know how ORFADIN affects you. ORFADIN is not known to cause dizziness or light headedness, but ORFADIN can affect your vision if you develop certain side effects.

Looking after your medicine	<ul style="list-style-type: none"> • Keep your capsules in the bottle until it is time to take them. • ORFADIN capsules should be stored in the box/bottle, in a refrigerator between 2°C - 8°C. Do not freeze. Alternatively, and for a period of 2 months only, ORFADIN capsules can also be stored in a cool dry place where the temperature stays below 25°C.
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For more information, see Section [5. What should I know while using ORFADIN?](#) in the full CMI.

6. Are there any side effects?

If you do experience any side effects, most of them are minor and temporary. Tell your doctor immediately if you experience red eyes, clouding or inflammation of the eyes, inflammation of the eyelid, sensitivity to light, or eye pain. Call your doctor straight away or go to the Emergency Department at your nearest hospital if you experience shortness of breath, wheezing or difficulty breathing, or swelling of the face, lips, tongue or other parts of the body. 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.

ORFADIN Capsules

Active ingredient(s): *nitisinone*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using ORFADIN?

ORFADIN contains the active ingredient nitisinone.

Nitisinone belongs to a group of medicines called 'other alimentary and metabolism products'.

ORFADIN is used for the treatment of a disease called hereditary tyrosinaemia type 1 (HT-1).

In this disease the body is unable to completely break down the amino acid tyrosine. Harmful substances can form and accumulate in the body.

ORFADIN blocks the breakdown of tyrosine and by doing so the harmful substances are not formed. However, tyrosine will remain in the body and therefore a special diet that is low in tyrosine and phenylalanine content must be followed when taking ORFADIN.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

2. What should I know before I use ORFADIN?

Diet

Tell your doctor about your diet regimen.

Your doctor will advise you on how to maintain a diet restricted in tyrosine and phenylalanine content.

Do not use ORFADIN if:

- you are allergic to nitisinone, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

- **Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**
- If it has expired or is damaged, return it to your pharmacist for disposal.
- **If you are not sure whether you should start taking this medicine, talk to your doctor.**

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.

Your doctor can discuss with you the risks and benefits involved.

Do not breastfeed if you are taking this medicine.

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

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 ORFADIN and affect how it works. These include:

- warfarin, a medicine used to thin your blood
- phenytoin, a medicine used to treat epilepsy
- furosemide (frusemide), a diuretic

These medicines may be affected by ORFADIN or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking ORFADIN.

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

4. How do I use ORFADIN?

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

How much to take

- The recommended starting dose is 1 mg/kg body weight/day divided in 2 doses administered orally. Your doctor will prescribe the correct dose for you.
- Your doctor may change your total dose from twice a day to once a day if you weigh more than 20 kg and you have been taking ORFADIN twice daily for at least 4 weeks.
- **Your doctor will adjust your ORFADIN dose based on your response to ORFADIN and your test results.**

When to take ORFADIN

- If you are taking ORFADIN twice daily, take your first dose in the morning and your second dose in the evening.
- Your doctor will advise you on the correct time to take ORFADIN when moving you to once daily dose.
- **Take your medicine at about the same time each day.**
- Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How to take ORFADIN

- **Take ORFADIN with food.**

- **Swallow the capsule whole with a full glass of water.**
- If you have problems with swallowing the capsules, you may open the capsule and mix the powder with a small amount of water or formula just before you take it, making sure that you take the entire amount.

How long to take ORFADIN

Continue taking ORFADIN for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take ORFADIN

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

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much ORFADIN

If you think that you have taken too much ORFADIN, 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 ORFADIN?

Things you should do

It is very important that you stay on the special diet, with low tyrosine and phenylalanine content that your doctor recommended. If you do not understand the instructions on your diet, ask your doctor for help.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking ORFADIN.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking ORFADIN.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking ORFADIN.

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

- Your doctor will do regular blood and urine checks to ensure that you are on the right dose of ORFADIN and to make sure that there are no possible side effects causing blood disorders.
- Your doctor will also check your liver regularly as the disease can affect the liver.
- Your doctor will also check on your general development.

Call your doctor straight away if you:

If you experience red eyes, or any of the following eye problems, tell your doctor immediately.

Your doctor will immediately check your eyes.

Eye problems could be a sign of inadequate dietary control.

Different eye symptoms as listed below:

- scarring or clouding of the cornea
- inflammation in the cornea
- inflammation in the eye
- inflammation in the eyelid

- sensitivity to light
- eye pain

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

Things you should not do

- **Do not take ORFADIN to treat any other complaints unless your doctor tells you to.**
- **Do not give ORFADIN to anyone else, even if they have the same condition as you.**
- **Do not stop taking ORFADIN or lower the dosage without checking with your doctor.**
- If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects.
- **Do not breastfeed while taking ORFADIN.**

Driving or using machines

Be careful driving or operating machinery or doing other jobs until you know how ORFADIN affects you.

ORFADIN is not known to cause dizziness or light headedness, but ORFADIN can affect your vision if you develop certain side effects.

Looking after your medicine

Keep your capsules in the bottle until it is time to take them.

If you take the capsules out of the bottle they may not keep well.

ORFADIN capsules should be stored in the box/ bottle, in a refrigerator between 2°C - 8°C. Do not freeze.

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

Alternatively, and for a period of 2 months only, ORFADIN capsules can also be stored in a cool dry place where the temperature stays below 25°C.

To help you remember, write the discard date in the space provided on the ORFADIN bottle when you stop refrigerating.

After this period, discard all ORFADIN capsules that have not been refrigerated.

Do not store ORFADIN or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car, especially on hot or cold days.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

When to discard your medicine

If not refrigerated, ORFADIN Capsules must be discarded after 2 months.

To help you remember, write the discard date in the space provided on the ORFADIN bottle when you stop refrigerating.

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
General: <ul style="list-style-type: none">• rash• itching or irritating sensation of skin• redness and peeling of skin• headache• stomach pain• constipation	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
<p>Eye-related:</p> <ul style="list-style-type: none">• red eyes• scarring or clouding of the cornea• inflammation in the cornea• inflammation in the eye• inflammation in the eyelid• sensitivity to light• eye pain <p>Allergic reaction:</p> <ul style="list-style-type: none">• shortness of breath• wheezing or difficulty breathing• swelling of the face, lips, tongue or other parts of the body• rash, itching or hives on the skin	<p>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.</p>

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.

There may be other side effects affecting your liver and certain blood cell counts that your doctor will carefully monitor by doing regular blood and urine checks.

Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

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.

ORFADIN is not addictive.

What ORFADIN contains

Active ingredient (main ingredient)	Each ORFADIN capsule contains either 2 mg, 5 mg, 10 mg, or 20 mg of nitisinone.
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• Pregelatinised maize starch• Gelatin• Titanium dioxide• Printing ink: Capsugel Ink 10A1 Black (Proprietary Ingredient Number 109522) or• Printing ink: Capsugel Ink 10A2 Black (Proprietary Ingredient Number 109521)
Potential allergens	None

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

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

What ORFADIN looks like

ORFADIN capsules are white, opaque, hard gelatin capsules, imprinted with "NTBC" and the strength "2 mg", "5 mg" "10 mg" or "20 mg" in black.

The capsules contain a white to off-white powder.

ORFADIN capsules are available in plastic bottles with child resistant closures.

Each bottle contains 60 capsules.

Who distributes ORFADIN

ORFADIN is supplied by:

A. Menarini Australia Pty. Ltd.

Sydney, Australia

Medical Information: 1800 644 542

Australian Registration Number:

ORFADIN 2 mg: AUST R 164163

ORFADIN 5 mg: AUST R 164173

ORFADIN 10 mg: AUST R 164174

ORFADIN 20 mg: AUST R 297735

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This leaflet was prepared in September 2025.

For the most up to date version of this leaflet, please go to www.menarini.com.au/cmi

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