

ORFADIN® 2 mg, 5 mg, 10 mg

Nitisinone

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Orfadin hard capsules. It does not contain all of the available information. Reading this leaflet does not take the place of talking to your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of your taking Orfadin against the benefits they expect it will have for you.

If you have any concerns about taking Orfadin, ask your doctor.

Keep this leaflet with the medicine. You may want to read it again.

What ORFADIN is used for

Orfadin contains a medicine called nitisinone which is used for the treatment of a disease called hereditary tyrosinaemia type 1. In this disease the body is unable to completely break down the amino acid tyrosine. Harmful substances will be formed and accumulated 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 (with low tyrosine and phenylalanine content) must be followed when taking Orfadin.**

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

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

Your doctor may have prescribed it for another use.

Orfadin is not addictive.

Orfadin is only available on a doctor's prescription.

Before you take ORFADIN

You should discuss with your doctor if you:

- have a history of hypersensitivity (an allergy) to the active substance or any of the other ingredients listed at the end of this leaflet. Signs of allergic reactions may include itchy skin, rash, shortness of breath and swelling of the face or tongue.
- are breast-feeding.

Do not take Orfadin if the packaging is torn or seems to have been opened.

Do not take Orfadin after the expiry date printed on the bottle.

Before you start to take ORFADIN

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you are pregnant or plan to become pregnant or are breast feeding.

Taking other medicines

Tell your doctor about all other medications that you are taking, even ones that you can buy without a

prescription from your pharmacy, supermarket or health food shop.

Your doctor can tell you which medicines you can safely take with Orfadin.

How to take ORFADIN

It is important to follow the directions that your doctor has given to you.

How much to take

Always take Orfadin exactly as your doctor has told you. You should check with your doctor if you are not sure.

When to take it

The usual daily dose is 1 mg/kg body weight divided in morning and evening administrations.

Take your first dose in the morning. Take your second dose in the evening. Take your medicine with food.

Swallow the capsules whole with a full glass of water. If you have problems with swallowing the capsules, they may be opened and the powder suspended into a small amount of water or formula diet just before intake.

How long to take it

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

If you forget to take it

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

If you take too much (overdose)

Telephone your doctor or Poisons Information Centre (13 11 26) if you think that you have taken more than you should.

While you are taking ORFADIN

Things you must do

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

Make sure that all of your doctors and pharmacists know about your use of Orfadin. Remind them if any new medicines are about to be started.

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

Be sure to keep all of your doctor's appointments so your progress can be checked.

- Your doctor will test your blood to check if the amounts of Orfadin given are enough 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.

Things you must not do

Do not use Orfadin to treat any complaint other than that directed by your doctor. It may not be safe to use Orfadin for another complaint.

Do not give Orfadin to someone else even if their symptoms are the same. It may not be safe for another person to use Orfadin.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert until you know how this medicine affects you.

Side effects

Tell your doctor or pharmacist as soon as possible if you feel unwell while you are taking Orfadin. Like all medicines, Orfadin may have some side effects. Most side effects are mild and patients often find that these wear off after a few weeks.

Tell your doctor immediately if you notice any of the following:

- different eye symptoms as listed below:
 - opacity in the cornea
 - inflammation in the cornea
 - inflammation in the eye
 - inflammation in the eyelid
 - sensitivity to light
 - eye pain
- rash, itching or other skin disorders
- headache, abdominal pain, constipation

There may be other side effects that your doctor will carefully monitor by taking blood samples. These are:

- reduced number of platelets and white blood cells
- shortage of certain white blood cells (granulocytopenia)
- increased number of white blood cells

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell. Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using ORFADIN

Storage

- Keep Orfadin capsules in their bottle until it is time to take your dose. If you take them out of their container, they may not keep well.
- Keep Orfadin in a refrigerator (2°C - 8°C).
- Do not leave it in the car on hot or cold days. Heat and dampness can destroy some medicines.
- Keep Orfadin where children cannot reach it.

Disposal

Return any unused medicine to your doctor.

Product description

What Orfadin looks like

Orfadin capsules are white, opaque, hard gelatin capsules, imprinted with "NTBC" and the strength "2 mg", "5 mg" or "10 mg" in black. The capsules contain a white to off-white powder.

Ingredients

Each Orfadin capsule contains 2 mg, 5 mg or 10 mg nitisinone.

It also contains the following inactive ingredients:

- starch - pregelatinised maize
- gelatin
- titanium dioxide
- Capsugel Ink 10A1 Black (Proprietary Ingredient Number 109522)
- Capsugel Ink 10A2 Black (Proprietary Ingredient Number 109521)

Orfadin capsules are available in plastic bottles with child resistant closures. Each bottle contains 60 capsules.

Manufacturer/Supplier

Orfadin capsules are made in Sweden by Apotek Produktion & Laboratorier AB and are supplied in Australia by:

A. Menarini Australia Pty. Ltd.
Level 8, 67 Albert Avenue
CHATSWOOD NSW 2067
Customer Information 1800 644 542
www.menarini.com.au

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ORFADIN 10 mg: AUST R 164174

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