

Nitisinone DiPharma 2 mg hard capsules

Nitisinone DiPharma 5 mg hard capsules

Nitisinone DiPharma 10 mg hard capsules

nitisinone

What is in this leaflet

Please read this leaflet carefully before you start using Nitisinone DiPharma.

This leaflet answers some common questions about Nitisinone DiPharma. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Nitisinone DiPharma against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

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

What Nitisinone DiPharma is used for

The active ingredient of Nitisinone DiPharma is nitisinone. This medicine is used for treatment of a rare disease called hereditary tyrosinemia type 1 in adults, adolescents and children (in any age range).

In this disease your body is unable to completely break down the amino acid tyrosine (amino acids are building blocks of our proteins), forming harmful substances. These substances are accumulated in your body. Nitisinone DiPharma blocks the breakdown of tyrosine and the harmful substances are not formed.

You must follow a special diet while you are taking this medicine, because tyrosine will remain in your body. This special diet is based on low tyrosine and phenylalanine (another amino acid) content.

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

This medicine is available only with a doctor's prescription.

Before you use Nitisinone DiPharma

When you must not use it

Do not use Nitisinone DiPharma if:

- if you are allergic to nitisinone or any of the other ingredients of this medicine (listed below in Ingredients).

Do not breast-feed while taking this medicine, see section “Pregnancy and breast-feeding”.

If you are not sure whether you should start using Nitisinone DiPharma, talk to your doctor.

Before you start to use it

Tell your doctor if:

- you get red eyes or any other signs of effects on the eyes. Contact your doctor immediately for an eye examination. Eye problems could be a sign of inadequate dietary control (see “Side effects”).

If you have not told your doctor about any of the above, tell them before you start using Nitisinone DiPharma.

During the treatment, blood samples will be drawn in order for your doctor to check whether the treatment is adequate and to make sure that there are no possible side effects causing blood disorders.

Your liver will be checked at regular intervals because the disease affects the liver.

Follow-up by your doctor should be performed every 6 months. If you experience any side effects, shorter intervals are recommended.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Nitisinone DiPharma.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Nitisinone DiPharma.

How to use Nitisinone DiPharma

If you start treatment by taking it with food, it is recommended that you carry on taking it with food throughout your course of treatment.

How much to take

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Treatment with this medicine should be started and supervised by a doctor experienced in the treatment of the disease (hereditary tyrosinemia type 1).

The recommended total daily dose is 1 mg/kg body weight administered orally. Your doctor will adjust the dose individually.

It is recommended to administer the dose once daily. However, due to the limited data in patients with body weight <20 kg, it is recommended to divide the total daily dose into two daily administrations in this patient population.

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 diet just before you take it.

How long to take it

If you have the impression that the medicine is not working properly, talk to your doctor. Do not change the dose or stop the treatment without talking to your doctor.

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

If you forget to take it

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, contact your doctor or pharmacist.

While you are using Nitisinone DiPharma

Things you must do

The safety of this medicine has not been studied in pregnant and breast-feeding women.

Please contact your doctor if you plan to become pregnant. If you become pregnant you should contact your doctor immediately.

Do not breast-feed while taking this medicine, see section “Do not take Nitisinone DiPharma”.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Nitisinone DiPharma.

Things you must not do

Do not give Nitisinone DiPharma to anyone else, even if they have the same condition as you. Do not change the dose or stop the treatment without talking to your doctor.

Things to be careful of

This medicine has minor influence on the ability to drive and use machines. However, if you experience side effects affecting your vision you should not drive or use machines until your vision is back to normal (see “Side effects”).

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Nitisinone DiPharma.

Do this even if there are no signs of discomfort or poisoning.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Nitisinone DiPharma.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects. Ask your doctor or pharmacist to answer any questions you may have.

If you notice any side effects relating to the eyes, talk to your doctor immediately to

have an eye examination. Treatment with nitisinone leads to higher levels of tyrosine in the blood which can cause eye related symptoms. Common eye related side effects (may affect more than 1 in 10 people) caused by higher tyrosine levels are inflammation in the eye (conjunctivitis), opacity and inflammation in the cornea (keratitis), sensitivity to light (photophobia) and eye pain. Inflammation of the eyelid (blepharitis) is an uncommon side effect (may affect up to 1 in 100 people).

Other common side effects

- Reduced number of platelets (thrombocytopenia) and white blood cells (leukopenia), shortage of certain white blood cells (granulocytopenia).

Other uncommon side effects

- increased number of white blood cells (leucocytosis),
- itching (pruritus), skin inflammation (exfoliative dermatitis), rash.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

After using Nitisinone DiPharma

Storage

Keep Nitisinone DiPharma where the temperature stays below 30°C. 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 bottle and the carton after "EXP". The expiry date refers to the last day of that month.

Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

Product description

What it looks like

The hard capsules are white, opaque, imprinted with the strength "2", "5" or "10" and the "company logo", in dark blue. The capsule contains a white to off-white powder. The capsules are packaged in a HDPE bottle with a tamper-proof closure of PP, containing 60 capsules. Each bottle contains 60 capsules. Each pack contains 1 bottle.

Ingredients

What Nitisinone DiPharma contains

The active substance is nitisinone.

Nitisinone DiPharma 2 mg: Each capsule contains 2 mg nitisinone.

Nitisinone DiPharma 5 mg: Each capsule contains 5 mg nitisinone.

Nitisinone DiPharma 10 mg: Each capsule contains 10 mg nitisinone.

The other ingredients are

Capsule content:

- Starch, pregelatinised (Starch 1500)
- stearic acid

Capsule shell:

- gelatin

Printing ink:

- shellac,
- propylene glycol,
- strong ammonia solution,
- Indigotine FD&C blue aluminium lake (E132)

Sponsor Details

Nitisinone DiPharma is supplied in New Zealand by:

Te Arai BioFarma Ltd

PO Box 46205

Herne Bay

Auckland, 1147

NEW ZEALAND

0800 TEARAI (832724)

Nitisinone DiPharma is manufactured by:

Doppel Farmaceutici srl

Via Volturmo 48

20089 Quinto de' Stampi (MI) – Italy

For

Dipharma S.A.

Piazza Col. C. Bernasconi, 56830, Chiasso – Switzerland

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