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Package leaflet: Information for the patient

Naftidrofuryl 100mg capsules

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1 What Naftidrofuryl capsules are and what they are used for

Naftidrofuryl capsules belong to a group of medicines called vasodilators. This medicine helps improve blood flow in the body.
Naftidrofuryl capsules are used to treat:
- poor blood supply, causing:
  - cramps, usually in the calf and leg muscles, during walking or exercise or in the legs at night.
  - pains whilst resting, usually in the feet.
  - gangrene.
  - ulcers on the skin.
  - painful, numb, cold or blue fingers (Raynaud's syndrome).
  - blue hands and feet.
  - disease of the arteries caused by diabetes.

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2 What you need to know before you take Naftidrofuryl capsules

Do not take Naftidrofuryl capsules if you:
- are **allergic** to naftidrofuryl oxalate or any of the other ingredients of this medicine (listed in section 6).
- have a history of excessive amounts of **oxalic acid (oxalates) in the urine** or **recurrent calcium stones** such as kidney stones.

Warnings and Precautions

Talk to your doctor or pharmacist before taking Naftidrofuryl capsules.
Cases of liver damage have been reported with naftidrofuryl. If you show signs of liver damage, you must stop taking Naftidrofuryl capsules.

Use in children and adolescents

Not recommended.

Other medicines and Naftidrofuryl capsules

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may become pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

This medicine contains less than 1mmol sodium (23mg) per capsule, that is to say essentially 'sodium-free'.

3 How to take Naftidrofuryl capsules

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

The recommended dose is
Adults and Elderly
One or two capsules three times a day for at least three months.

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Swallow the capsules with a glass of water, with or after food, **do not chew them**. It is important to drink plenty of water while you are taking this medicine.

If you take more Naftidrofuryl capsules than you should

If you (or someone else) swallow a lot of capsules at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Overdose may cause heart problems or fits.

If you forget to take Naftidrofuryl capsules

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time.

If you stop taking Naftidrofuryl capsules

Do not stop taking Naftidrofuryl capsules unless your doctor tells you to, even if you feel better.

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

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any of the following side effects with Naftidrofuryl capsules, **STOP taking the capsules, contact your doctor immediately and consider attending hospital casualty:**

A severe allergic reaction, such as itching, swelling of the face, lips, tongue, mouth, or throat, which may cause shortness of breath, wheezing, or difficulty breathing.

Rare (may affect up to 1 in 1,000 people):
Liver damage (may cause yellowing of the skin and eyes)

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

Uncommon (may affect up to 1 in 100 people):
Diarrhoea, feeling or being sick, stomach pain, skin rash

Very rare (may affect up to 1 in 10,000 people):
Kidney stones

Not known (frequency cannot be estimated from the available data):
Inflammation in the throat when capsule not taken with sufficient amount of liquid.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Naftidrofuryl capsules

Keep out of the sight and reach of children.
Store below 25°C in a dry place. Protect from light.
Do not take this medicine after the expiry date stated on the carton after EXP. The expiry date refers to the last day of that month.
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 protect the environment.

6 Contents of the pack and other information

What Naftidrofuryl capsules contain

- The active substance (the ingredient that makes the capsule work) is naftidrofuryl oxalate. Each capsule contains 100mg of the active ingredient.
- The capsule contains: maize starch, microcrystalline cellulose (E460), sodium starch glycollate, colloidal silica, stearic acid, magnesium stearate.
- The capsule shell contains: erythrosine (E127), titanium dioxide (E171), gelatin.
- The printing ink contains: Shellac (E904), propylene glycol (E1520), iron oxide black (E172) and potassium hydroxide (E525).

What Naftidrofuryl capsules look like and contents of the pack

Naftidrofuryl are pink, hard gelatin capsules (size 2) printed "C" and "NL" in black.

Pack sizes are 84 capsules.

Marketing Authorisation Holder and Manufacturer
Accord, Barnstaple, EX32 8NS, UK.

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