

Package leaflet: Information for the user

Nefopam Hydrochloride 30mg Film-coated Tablets

nefopam

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 Nefopam Tablets is and what it is used for

The name of your medicine is Nefopam Hydrochloride 30mg Film-coated Tablets (referred to as Nefopam Tablets throughout this leaflet). Nefopam Tablets belong to a group of medicines called analgesics, commonly known as pain killers or pain relievers.

The active substance, nefopam, interrupts the pain messages being sent to your brain, and it also acts in your brain to stop pain messages being felt. This means that Nefopam Tablets do NOT stop the pain from happening, but you will not be able to feel the pain as much.

Nefopam Tablets are used to relieve acute and chronic pain (for example pain after an operation, dental pain, joint or muscle pain, after an injury, or pain caused by cancer). Nefopam Tablets should NOT be used to treat the pain from a heart attack.

2. What you need to know before you take Nefopam Tablets

Do not take Nefopam Tablets

- if you are a child under 12 years old
- if you are allergic to nefopam or any of the other ingredients of this medicine (listed in section 6), particularly if resulting in a skin rash, swelling of the face or difficulty in breathing (see section 4)
- if you are taking monoamine oxidase inhibitors (MAOIs) to treat your depression (see “Other medicines and Nefopam Tablets”)
- if you have, or have ever had, epilepsy (fits).

Warnings and precautions

Talk to your doctor or pharmacist before taking Nefopam Tablets if:

- you have severe problems with your liver or kidneys
- you have, or have had in the past difficulty passing urine
- you have problems with your heart
- you were previously diagnosed with glaucoma (increased pressure in the eye).

Children

Nefopam Tablets are NOT recommended for children under 12 years old (see section 3).

Other medicines and Nefopam Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without prescription.

In particular, tell your doctor if you are taking or have recently taken the following medicines:

- monoamine oxidase inhibitors (known as MAOIs) for depression. Nefopam Tablets and MAOIs must NOT be taken together.
- tricyclic antidepressants for depression
- benzodiazepines
- opioids
- anticholinergics
- sympathomimetics.

Tell your doctor or dentist if you are taking any of these medicines.

Pregnancy and breast-feeding

Nefopam Tablets should NOT be taken during pregnancy or while breast-feeding.

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

Driving and using machines

Nefopam Tablets can cause drowsiness. You should NOT drive or use machines when you first start to take this medicine until you are certain that you are not getting any side effects. If in any doubt, speak to your doctor before you drive or use machines.

3. How to take Nefopam Tablets

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 as follows:

Dosage for adults:

- The recommended initial dose is **two tablets taken three times a day**. Your doctor may increase this dose up to a maximum of three tablets taken three times a day according to your needs
- Nefopam dose can be as low as 1 tablet per day
- Swallow your tablets with water.

Ask your doctor or pharmacist if:

- you are not sure how many tablets to take or when to take them.
- you think the effect is too strong or too weak.

Use in children and adolescents

- Over 12 years - as per adults (see above).
- Under 12 years - **Nefopam Tablets are NOT to be taken by children under 12 (see section 2, "Children")**.

Dosage for elderly patients:

In elderly patients the doctor may reduce the number of tablets that are taken.

Dosage for patients with kidney and/or liver problems:

Your doctor may adjust the dose of Nefopam Tablets depending upon your condition.

If you take more Nefopam Tablets than you should

If you think that you, or any other person, may have taken too many tablets, **contact your doctor or hospital casualty department immediately**. Over dosage can cause symptoms such as seizure, disturbance in thinking and perception, unconsciousness, anxiety, fast resting heart rate and abnormally increasing circulatory volume. Take any remaining tablets and this leaflet with you so that the medical staff knows exactly what you have taken.

If you forget to take Nefopam Tablets

If you forget to take Nefopam Tablets, take it as soon as you remember. Do NOT take a double dose to make up for a forgotten dose.

If you stop taking Nefopam Tablets

Do NOT stop taking Nefopam Tablets without checking with your doctor first.

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 or someone you know taking this medicine experiences any of the following side effects, STOP taking this medicine and contact your doctor IMMEDIATELY:

- swelling of the skin and soft tissue around the eyes, nose and throat with difficulty breathing (angioedema)
- allergic reactions-like hives (itchy red spots on the skin), itching, nasal congestion (known as rhinitis), rash, watery or itchy eyes, coughing, fainting, dizziness, confusion, or weakness.
- convulsion
- coma.

Other side effects include:

Not known: frequency cannot be estimated from the available data

- feeling sick (nausea)
- feeling light-headed, dizzy or nervous, or fainting
- a decrease in blood pressure
- numbness or tingling in the extremities
- a dry mouth
- having difficulty passing urine
- tremor
- confusion
- hallucinations (seeing things that are not there)
- being sick (vomiting)
- abdominal pain or diarrhoea
- blurred vision
- drowsiness
- sweating
- trouble sleeping
- headaches
- awareness of your heartbeat (palpitations), or a fast heartbeat (tachycardia).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: 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 Nefopam Tablets

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 carton and blister 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 Nefopam Tablets contain

- The active substance is nefopam hydrochloride 30mg.
- The other ingredients are calcium hydrogen phosphate dihydrate, cellulose microcrystalline, starch pregelatinised, hydrogenated vegetable oil, silica colloidal anhydrous and magnesium stearate.

The coating consists of hydroxyl propyl methylcellulose 2910/hypromellose, titanium dioxide (E171) macrogol/polyethylene glycol and purified water.

What Nefopam Tablets look like and contents of the pack

Nefopam Tablets are white to off white, round, biconvex film coated tablets with 'NFP' debossed on one side and plain on other side. The tablets are supplied in blister packs of 90 tablets.

Marketing Authorisation Holder

Focus Pharmaceuticals Limited,
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Manufacturer

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