

PACKAGE LEAFLET

Package leaflet: Information for the patient
Nefopam hydrochloride 30 mg film-coated tablets

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

Name of the product will be referred to as 'nefopam hydrochloride tablets' throughout the leaflet.

What is in this leaflet

1. What Nefopam hydrochloride tablet is and what it is used for
2. What you need to know before you take Nefopam hydrochloride tablet
3. How to take Nefopam hydrochloride tablet
4. Possible side effects
5. How to store Nefopam hydrochloride tablet
6. Contents of the pack and other information

1. What Nefopam hydrochloride tablet is and what it is used for

Nefopam hydrochloride tablet belongs to a group of medicines called analgesics, commonly known as pain killers or pain relievers. The active substance, nefopam hydrochloride, 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 hydrochloride does not stop the pain from happening, but you will not be able to feel the pain as much.

Nefopam hydrochloride is used to relieve of 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 hydrochloride should not be used to treat the pain from a heart attack

2. What you need to know before you take Nefopam hydrochloride tablet

Do not take nefopam hydrochloride if:

- you are a child under 12 years old
- you have ever had an allergic reaction to nefopam hydrochloride or any of the ingredients resulting in a skin rash, swelling of the face or difficulty in breathing (see section 6. Contents of the pack and other information)
- you are taking monoamine oxidase inhibitors (MAOIs) to treat your depression
- you have, or have ever had, epilepsy (fits).

Warnings and precautions

Talk to your doctor or pharmacist before taking nefopam hydrochloride

If the answer to any of the following is ‘yes’, you must tell your doctor – your doctor may decide to alter your treatment.

- Are you pregnant or breast feeding?
- Do you have severe problems with your liver or kidneys?
- Do you have, or have you had in the past difficulty passing urine?
- Are you taking other medicines?
- Have you previously been diagnosed with glaucoma (increased pressure in the eye)?

Children and adolescents

Nefopam hydrochloride should not be taken in children under 12 years.

If any of the above apply to you, your doctor may decide to alter your treatment.

Other medicines and Nefopam hydrochloride tablets

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

- Monoamine oxidase inhibitors (known as MAOIs) for depression. **You must tell your doctor** if you are taking this medicine.
- Tricyclic antidepressants for depression
- Anticholinergics
- Sympathomimetics

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

Pregnancy and 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.

Nefopam hydrochloride should not be taken during pregnancy or while breast-feeding. Please contact your doctor if you become pregnant during your treatment.

Driving and using machines

Nefopam hydrochloride can cause drowsiness. Do not drive or operate heavy machinery unless you know how nefopam hydrochloride affects you.

3. How to take Nefopam hydrochloride tablet

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

Dosage for adults:

The usual 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.

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

Swallow your tablets with water.

Dosage for children:

Over 12 years - as per adults (see above).

Under 12 years – **Nefopam hydrochloride should not be taken by children under 12.**

Dosage for older patients:

In older 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 hydrochloride depending upon your condition.

If you take more Nefopam hydrochloride tablets than you should

If you accidentally take more tablets than your prescribed dose, tell your doctor or pharmacist immediately and if necessary contact your nearest hospital casualty department. Remember to take the pack and any remaining medicines with you.

If you forget to take Nefopam hydrochloride tablets

If you forget to take nefopam hydrochloride, 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 hydrochloride tablets

Do not stop taking nefopam hydrochloride without first checking with your doctor.

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

4. Possible side effects

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

Please stop taking this medicine and contact your doctor as soon as possible if you experience the following rare reactions:

- swelling of the skin and soft tissue around the eyes, nose and throat (angioedema), or allergic reactions (anaphylaxis).

Side-effects which may occur most frequently include:

- feeling sick
- 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
- convulsions (fits), tremor
- confusion
- hallucinations (seeing things that aren't there).

Other side-effects which may occur less frequently include:

- being sick
- abdominal pain or diarrhoea
- blurred vision
- drowsiness
- sweating
- trouble sleeping
- headaches
- awareness of your heartbeat (palpitations), or a fast heartbeat (tachycardia).

- coma

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.co.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 hydrochloride tablets

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the blister label and the carton after EXP. The expiry date refers to the last day of that month.

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

6. Contents of the pack and other information

What Nefopam hydrochloride tablet contains

- The active substance is nefopam hydrochloride
- The other ingredients are:

Tablet Core:

Microcrystalline cellulose,
Pregelatinized starch,
Dicalcium phosphate dihydrate,
Silica colloidal anhydrous,
Magnesium stearate,

Tablet Film-coating:

Hypromellose (6cP),
Titanium dioxide (E171),
Macrogol

What Nefopam hydrochloride tablet looks like and contents of the pack

Nefopam hydrochloride tablets are white to off white, round shape, film coated tablets debossed with "EM" on one side and "62" on the other side

The tablets are available in aluminium-PVC/PVDC blister or aluminium-PVC blister with 30's and 90's tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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This leaflet was last revised in March 2024