Package leaflet: Information for the user

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 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.
- The full name of this medicine is Nefopam Hydrochloride 30 mg Film-coated Tablets but within the leaflet it will be referred to as Nefopam Tablets.

What is in this leaflet

1. What Nefopam Tablets are and what they are used for

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

Warnings and precautions
Talk to your doctor or pharmacist before taking Nefopam Tablets. 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?

Children
Do not give this medicine to children under 12 years.

Other medicines and Nefopam 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
Nefopam Tablets should not be taken during pregnancy or while breast-feeding.
Ask your doctor or pharmacist for advice before taking any medicine. Please contact your doctor if you become pregnant during your treatment.

Driving and using machines
Nefopam Tablets can cause drowsiness. Do not drive or operate heavy machinery unless you know how Nefopam Tablets affects you.

Important information about some of the ingredients of Nefopam
This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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

3. How to take Nefopam Tablets

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

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.

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.

Use in children and adolescents
Over 12 years - as per adults (see above).
Under 12 years - **Nefopam Tablets should not be taken by children under 12.**

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

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 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 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 first checking with your doctor.

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.

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
- decrease in blood pressure
- numbness or tingling in the extremities
- dry mouth
- having difficulty passing urine
- convulsions, tremor
- 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
- confusion.

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
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 blister and carton. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 30 mg.
- The other ingredients are: Lactose, Silica colloidal anhydrous, Cellulose microcrystalline, Sodium starch glycolate (type A), Magnesium stearate, Opadry II white 85F184221, Polyvinyl alcohol (E1203), Titanium dioxide (E171), Macrogol/PEG 3350 (E1521), Talc (E553b).

What Nefopam Tablets look like and contents of the pack
Nefopam Hydrochloride 30 mg Film-coated Tablets are white, round biconvex and marked 'A 55'on one side.

The tablets are packaged in blister packs of 90 tablets.

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