PACKAGE LEAFLET: INFORMATION FOR THE USER

Nefopam Hydrochloride 30 mg Film-coated tablets

nefopam hydrochloride

Read all of this leaflet carefully before you start using 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. Do not pass it on to others. It may harm them, even if their symptoms 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.

In this leaflet:

1. WHAT NEFOPAM TABLETS ARE AND WHAT THEY ARE USED FOR

The full name of your medicine is Nefopam Hydrochloride 30 mg Film-coated tablets. In this leaflet the shorter name Nefopam tablets is used.
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 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 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 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.
- You have ever had an allergic reaction to nefopam hydrochloride or any of the ingredients resulting in a skin rash, swelling of the face of 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

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?

Other medicines and Nefopam tablets
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes herbal medicines. This is because Nefopam tablets can affect the way some other medicines work.
Also some other medicines can affect the way Nefopam tablets work.
You must not take this medicine in combination with:
- Monoamine oxidase inhibitors (known as MAOIs) for depression. You must tell your doctor if you are taking this medicine.
- Tricyclic antidepressants for depressions
- Anticholinergics for relief of stomach cramps or spasms (e.g. hyoscine butylbromide, propantheline bromide)
- Sympathomimetics (e.g. pseudoephedrine)

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

Nefopam tablets with food, drink and alcohol
Not relevant.

Pregnancy, breast-feeding and fertility
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 or if you are planning to have a baby.

Driving and using machines
This medicine may cause drowsiness. Do not drive vehicles or use any tools or machines which require your attention.

3. HOW TO TAKE NEFOPAM TABLETS

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

Use in adults
The usual initial dose is one or 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

Use in children
Over 12 years – same as adults (see above)
Under 12 years - **Nefopam tablets should not be taken by children under 12.**

Use in older patients
In older patient 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 take more of this medicine than you should talk to a doctor or go to a hospital straight away. Take the medicine

Bozza no.: 1 / recto Data: 11.07.17 Colore: nero
Codice: 35204773 vers. 002 Formato: 190 x 240 mm
Pharmacode: dimensione 0.5 - 0.986 - 1.525 , posizione da 53.5 a 70 mm dal bordo
Lineagrafica sa 6596 Gordola

pack with you, even if there are no tablets left.
Medical treatment can be necessary.

If you forget to take Nefopam tablets
Do not take a double dose to make up for a forgotten dose.

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

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 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
- Dry mouth
- Having difficulty passing urine
- Convulsions, 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 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 at www.mhra.gov.uk/yellowcard. 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 store above 30°C.

Do not take Nefopam tablets after the expiry date which is stated on the carton and the blister foil 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.
Nefopam Hydrochloride 30 mg film-coated tablets:
each tablet contains 30 mg of nefopam hydrochloride.
The other ingredients are: cellulose microcrystalline, povidone (K30), hydrogen phosphate, copovidone, pregelatinised starch, silica colloidal anhydrous, magnesium. stearate. The film-coating contains HPMC 2910/Hypromellose and Titanium dioxide.

What Nefopam tablets look like and contents of the pack
Nefopam tablets are white, round, biconvex, film-coated tablets.

They are available in Alu/PVC-PE/PVDC blisters.

Packs of 30 and 90 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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Manufacturer

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