Package Leaflet: Information for the user

Nefopam Hydrochloride 30mg Tablets

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 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
1. What Nefopam Hydrochloride is and what it is used for
2. What you need to know before you use Nefopam Hydrochloride
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1. What Nefopam Hydrochloride is and what it is used for

The name of your medicine is Nefopam Hydrochloride 30mg Tablets (referred to as Nefopam Hydrochloride throughout this leaflet). Nefopam Hydrochloride includes the active substance nefopam hydrochloride. Nefopam Hydrochloride 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 use Nefopam Hydrochloride

Do not take Nefopam Hydrochloride:

◆ if you are a child under 12 years old
◆ if you are allergic to nefopam hydrochloride or any of the other ingredients of this medicine (listed in section 6)
◆ if you are taking monoamine oxidase inhibitors (MAOIs) to treat your depression
◆ if you have, or have ever had, epilepsy (fits).
◆ if you are pregnant or breast-feeding

Warnings and precautions

Talk to your doctor or pharmacist before using 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

Do not give this medicine to children between the ages of 0 to 12 years as the safety has not yet been established

Other medicines and Nefopam Hydrochloride

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

Tell your doctor, dentist or pharmacist if you are taking or have recently taken the medicines listed below:

• 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

Pregnancy, breast-feeding and fertility

Nefopam Hydrochloride 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. 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

Dosage for adults

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

The recommended dose is two tablets taken three times a day. Your doctor many 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 above.

Under 12 years – Nefopam Hydrochloride 30mg Tablets should not be taken by children under 12.

Use in older patients:

In older patients the doctor may reduce the number of tablets that are taken.
Use in 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 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
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
Do not stop taking Nefopam Hydrochloride 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
• a decrease in blood pressure
• numbness or tingling in the extremities
• a 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 Hydrochloride
Keep this medicine out of the sight and reach of children.
Keep your tablets in the original package.
Do not store above 30 °C.
Do not use this medicine after the expiry date which is stated on the carton.
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 Hydrochloride contains
• The active substance in Nefopam Hydrochloride 30mg Tablets is nefopam hydrochloride 30mg.
• The other ingredients are dibasic calcium phosphate dihydrate, microcrystalline cellulose, pregelatinised maize starch, magnesium stearate, hydrogenated vegetable oil, colloidal silicone dioxide, hydroxypropylmethylcellulose, titanium dioxide.

What Nefopam Hydrochloride looks like and contents of the pack
Nefopam Hydrochloride 30mg Tablets are round, white and marked ‘APN’ on one side. The tablets are packaged in blister packs of 90 tablets.

Market Authorisation Holder:
Mylan,
Potters Bar,
Hertfordshire,
EN6 1TL, UK

Manufacturer
3M Health Care Limited
Derby Road,
Loughborough,
Leicestershire.
LE11 5SF, UK

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Other sources of information
Is this leaflet hard to see or read? Please contact the MA holder at the address above.