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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.

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
3. How to use Nefopam hydrochloride
4. Possible side effects
5. How to store Nefopam hydrochloride
6. Contents of the pack and other information

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

The name of your medicine is Nefopam Hydrochloride 30 mg Film-coated 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. It 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 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
- you are **allergic** to active substance or any of the other ingredients of this medicine (listed in section 6).
- you are taking a medicine to **treat your depression** known as a monoamine oxidase inhibitor (MAOI)
- you have or have ever had **epilepsy** (fits).
- you are **pregnant** or **breast-feeding**

Warnings and precautions

Talk to your doctor before using Nefopam hydrochloride if:
– you have severe problems with your **liver or kidneys**
– you have or have had in the past **difficulty passing urine**
– you are taking **other medicines**
– you have previously been diagnosed with **glaucoma** (increased pressure in the eye)

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

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
Do not take Nefopam hydrochloride if you are taking a medicine to treat your depression known as a monoamine oxidase inhibitor (MAOI).

Tell your doctor, dentist or pharmacist if you are taking or have recently taken the medicines listed below:
- Tricyclic antidepressants for depression
- Anticholinergics
- Sympathomimetics

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

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.

Use of Nefopam hydrochloride may lead to dependence and abuse. If you have concerns that you may become dependent on Nefopam hydrochloride, it is important that you consult your doctor.

3. How to take Nefopam hydrochloride

Dosage
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 may increase this dose up to a maximum of three tablets taken three times a day, according to your needs.

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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.

How to take the tablets
The tablets are for oral use. They should be swallowed with a glass of water.

Use in children (under 12 years)
Nefopam hydrochloride should not be taken by children under 12 years.

Use in elderly 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 take more tablets than you should, tell your doctor or pharmacist immediately or contact your nearest hospital casualty department. Remember to take the pack and any remaining tablets 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.

STOP taking this medicine and contact your doctor immediately if you experience:
- swelling of the skin and soft tissue around the eyes, nose and throat with difficulty breathing (angioedema)
- allergic reactions (anaphylaxis)
- convulsions, tremor
- 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
- 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).

Rare (may affect up to 1 in 1,000 people):
- becoming dependent on Nefopam hydrochloride (drug dependence).

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.

5. How to Store Nefopam hydrochloride

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date, which is stated on carton and blister after EXP. The expiry date refers to the last day of that month.
- This medicinal product 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. Those measures will help protect the environment.

6. Contents of the pack and other information

What Nefopam hydrochloride contains
The active substance is nefopam hydrochloride 30 mg.

The other ingredients are calcium hydrogen phosphate dehydrate, microcrystalline cellulose, pregelatinised starch, colloidal anhydrous silica, magnesium stearate.

The coating material consists of hydroxypropyl methylcellulose, polyethylene glycol (6000 & 400) and titanium dioxide (E171).

What Nefopam hydrochloride looks like and contents of the pack
Nefopam hydrochloride 30 mg film-coated tablets are white to off white, round, film-coated biconvex tablets engraved with "20" on one side and "G" on the other side.

The tablets are available in Alu-Alu blister packs containing 90 tablets.

Marketing Authorisation Holder
Glenmark Pharmaceuticals Europe Limited
Laxmi House, 2B Draycott Avenue,
Kenton, Middlesex, HA3 0BU, United Kingdom

Manufacturer
Glenmark Pharmaceuticals Europe Limited
Building 2, Croxley Green Business Park,
Croxley Green, Hertfordshire
WD18 8YA, United Kingdom

Glenmark Pharmaceuticals s.r.o
Fibichova 143, 566 17 Vysoké Mýto
Czech Republic

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