

Package leaflet: Information for the user

Nefopam Hydrochloride 30mg 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.

What is in this leaflet:

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2. What you need to know before you take Nefopam Hydrochloride 30mg Film-Coated Tablets
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1. What Nefopam Hydrochloride 30mg Film-Coated Tablets are and what they are used for

Nefopam Hydrochloride 30mg Film-Coated 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 Hydrochloride 30mg Film-Coated Tablets do not stop the pain from happening, but you will not be able to feel the pain as much.

Nefopam Hydrochloride 30mg Film-Coated 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 Hydrochloride 30mg Film-Coated Tablets should not be used to treat the pain from a heart attack.

2. What you need to know before you take Nefopam Hydrochloride 30mg Film-Coated Tablets

Do not take Nefopam Hydrochloride 30mg Film-Coated Tablets if:

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

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Nefopam Hydrochloride 30mg Film-Coated Tablets if you

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

Children

Nefopam Hydrochloride 30mg Film-Coated Tablets should not be taken by children under 12 years old.

Other medicines and Nefopam Hydrochloride 30mg Film-Coated Tablets

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those obtained without a prescription and 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 30mg Film-Coated Tablets 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.

Driving and using machines

Nefopam Hydrochloride 30mg Film-Coated Tablets can cause drowsiness. Do not drive or operate machinery unless you know how Nefopam Hydrochloride 30mg Film-Coated Tablets affect you.

Nefopam Hydrochloride 30mg Film-Coated Tablets contain Lactose monohydrate.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Nefopam Hydrochloride 30mg Film-Coated Tablets

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:

12 years and over – as per adults (see above).

Under 12 years - **Nefopam Hydrochloride 30mg Film-Coated Tablets should not be taken by children under 12.**

Dosage for elderly patients:

In elderly 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 30mg Film-Coated Tablets depending on your condition.

If you take more Nefopam Hydrochloride 30mg Film-Coated 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 30mg Film-Coated Tablets

If you forget to take Nefopam Hydrochloride 30mg Film-Coated Tablets, take your dose as soon as you remember. Do not take a double dose to make up for the forgotten dose.

If you stop taking Nefopam Hydrochloride 30mg Film-Coated Tablets

Do not stop taking Nefopam Hydrochloride 30mg Film-Coated 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
- 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, 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.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nefopam Hydrochloride 30mg Film-Coated 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 carton and blister foil. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Keep your tablets in the original package.

Do not use this medicine if you notice that the pack or any of the tablets are damaged.

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 30mg Film-Coated Tablets contain

The active substance in Nefopam Hydrochloride 30mg Film-Coated Tablets is nefopam hydrochloride 30mg.

The other ingredients are calcium hydrogen phosphate dihydrate, microcrystalline cellulose, pregelatinised starch, magnesium stearate, hydrogenated vegetable oil and colloidal anhydrous silica.

The film-coat contains hypromellose (E464), titanium dioxide (E171), lactose monohydrate, macrogol and triacetin.

What Nefopam Hydrochloride 30mg Film-Coated Tablets look like and contents of the pack

Nefopam Hydrochloride 30mg Film-Coated Tablets are round, normal convex shaped, white, film-coated tablets debossed with 'N30' on one side and plain on the other.

The tablets are packaged in blister packs of 90 tablets.

Marketing Authorisation Holder

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Seagoe Industrial Estate
Craigavon
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UK

Manufacturer

Almac Pharma Services Limited
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20 Seagoe Industrial Estate
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