

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 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 name of your medicine is Nefopam Hydrochloride 30mg Film-coated tablets (referred to as Nefopam Hydrochloride throughout this leaflet).

What is in this leaflet

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

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 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 take Nefopam Hydrochloride

Do not take Nefopam Hydrochloride 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 or 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

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)?

Other medicines and Nefopam Hydrochloride

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without 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 (drugs which block acetylcholine, and can be used to treat conditions such as bowel spasm, overactive bladder and others) 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.

Pregnancy, breast-feeding and fertility

Nefopam Hydrochloride should not be taken during pregnancy or while breast-feeding.

Whether or not nefopam affects the fertility in humans is unknown.

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 your doctor or pharmacist if you are not sure.

The recommended starting dose is one to 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 Hydrochloride 30mg Film-coated 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 (see details below).

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

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

5. How to store Nefopam Hydrochloride

- Keep this medicine out of the sight and reach of children.
- This medicinal product does not require any special storage conditions.
- Do not use this medicine after the expiry date which is stated on the carton 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 to protect the environment.

6. Contents of the pack and other information

What Nefopam Hydrochloride contains

The active substance is Nefopam Hydrochloride. Each film-coated tablet contains 30 mg nefopam hydrochloride.

The other ingredients are microcrystalline cellulose, calcium hydrogen phosphate dihydrate, pregelatinised maize starch, colloidal anhydrous silica, magnesium stearate, hydrogenated castor oil, hypromellose, titanium dioxide.

What Nefopam Hydrochloride looks like and contents of the pack

Nefopam Hydrochloride 30mg Film-coated tablets are White to off-white, circular shaped, biconvex, film-coated tablets, debossed with 'NT' on one face and plain on other face, approximately 7.00 mm in diameter.

The tablets are packaged in blister packs of 30 or 90 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Brown & Burk IR limited

22 Northumberland Road,

Ballsbridge, Dublin 4, Ireland

Manufacturer

Brown & Burk UK Ltd

5 Marryat Close

Hounslow West

Middlesex

TW4 5DQ

UK.

This medicinal product is authorised in the Member States of the EEA under the following names:

UK: Nefopam Hydrochloride 30 mg Film-coated tablets.

IE: Nefopam Hydrochloride 30 mg Film-coated tablets.

This leaflet was last revised in 12/2020