

Description	Nefopam Leaflet		Colours Used
Market	UK		Black
Language	English		Keyline (Cutting Edge)
Size	210 x 297 mm		
Min. Font Size	Arial, 9 pt		
Page No.	1 of 1		
Version No.	7		
Date	19-05-2020		
Software	CorelDRAW 19		

PL00000-00
Pharmacode

Package Leaflet: Information for the User

Nefopam Hydrochloride 30 mg film-coated tablets Nefopam Hydrochloride

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.

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

What is in this leaflet:

1. What Nefopam Tablets is and what it is used for
2. What you need to know before you take Nefopam Tablets
3. How to take Nefopam Tablets
4. Possible side effects
5. How to store Nefopam Tablets
6. Contents of the pack and other information

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

Nefopam Tablets 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 Tablets does not stop the pain from happening, but you will not be able to feel the pain as much.

Nefopam Tablets 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 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
- if 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)
- if you are taking monoamine oxidase inhibitors (MAOIs) to treat your depression
- if 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?
- Have you previously been diagnosed with glaucoma (increased pressure in the eye)?

Other medicines and Nefopam tablets

Please **tell your doctor or pharmacist** if you are taking or have recently taken 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
 - Sympathomimetics
- Tell your doctor or dentist if you are taking any of these medicines.

Pregnancy and breast-feeding

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.

Driving and using machines

Nefopam Tablets can cause drowsiness. Do not drive or operate heavy machinery unless you know how Nefopam Tablets affects you.

3. How to take Nefopam Tablets

Dosage for adults:

Always take Nefopam Tablets exactly as your doctor has told you.

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:

Over 12 years - as per adults (see above).

Under 12 years - **Nefopam Tablets should not be taken by children under 12.**

Dosage for older patients:

In older 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 Tablets depending upon your condition.

If you take more Nefopam 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 Tablets

If you forget to take Nefopam Tablets, take it as soon as you remember. Do not take more than one dose at the same time to make up for the forgotten dose.

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 Nefopam Tablets 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).

Frequency not known

- coma
- confusion

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 Website: www.medicinesauthority.gov.mt/adportal. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nefopam Tablets

Keep your tablets in the original package and out of the sight and reach of children.

Do not use Nefopam Tablets after the expiry date shown on the carton, even if there are some tablets left. Ask your doctor to replace them with a new prescription and take any unused tablets back to the pharmacy.

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

Description and contents of Nefopam Tablets

- The active substance is Nefopam Hydrochloride. Each film-coated tablet contains Nefopam hydrochloride 30 mg
- The other ingredients are: Calcium hydrogen phosphate dehydrate, Microcrystalline cellulose, Hypromellose, Colloidal anhydrous silica, Magnesium stearate

Coating ingredients: Hypromellose (E464), Hydroxy propyl cellulose (E463), Titanium dioxide (E171)

What Nefopam Tablets looks like and contents of the pack

Nefopam Tablets are white round film-coated tablets, marked with '30N' on one side and smooth on other side.

Nefopam Tablets is available in Blister packs of PVC- Aluminium foil, containing 10 tablets in a 10, 20, 30, 50, 60, 90 and 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

The Marketing Authorisation Holder for your tablet is:

RIA Generics Limited
The Black Church
St. Mary's Place, Dublin 7
D07 P4AX, Ireland

Manufacturer:

Wave Pharma Limited,
4th Floor Cavendish House, 369 Burnt Oak,
Edgware, Middlesex, HA85AW, UK

If you would like this leaflet in different format information or want to report any side effects please contact marketing authorisation holder listed above.

This leaflet was last revised in May 2020