

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Acupan® 30mg Tablets

(nefopam hydrochloride)

This product is available as the above name but will be referred to as Acupan throughout the following leaflet.

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.

In this leaflet:

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

1. What Acupan is and what it is used for

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

Acupan 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). Acupan should not be used to treat the pain from a heart attack.

2. What you need to know before you take Acupan

Do not take Acupan 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).

Take special care with Acupan

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)?

Taking other medicines

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

Acupan 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

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

3. How to take Acupan

Dosage for adults:

Always take Acupan 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 - **Acupan 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 Acupan depending upon your condition.

If you take more Acupan 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 Acupan

If you forget to take Acupan, 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 Acupan

Do not stop taking Acupan 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 Acupan 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 Acupan

- Keep out of the sight and reach of children.
- Do not store above 30°C.
- Do not use Acupan after the expiry date shown on the carton, even if there are some tablets left. The expiry date refers to the last day of that month. Ask your doctor to replace them with a new prescription and take any unused tablets back to the pharmacy.
- If your medicine becomes discoloured, or shows any signs of deterioration, consult your pharmacist who will tell you what to do.
- Ask your pharmacist how to dispose of medicines no longer required. Do not dispose of medicines by flushing down a toilet or sink or by throwing out with your normal household rubbish. This will help protect the environment.

6. Contents of the pack and other information

Description and contents of Acupan

The active substance in Acupan is nefopam hydrochloride. Each film-coated tablet contains 30mg of nefopam hydrochloride.

The other ingredients are colloidal silicone dioxide, calcium hydrogen phosphate dihydrate, microcrystalline cellulose, hydrogenated vegetable oil, maize starch, magnesium stearate, hypromellose 2910 (15CPS), titanium dioxide.

Acupan are white, round, film-coated tablets, marked 'APN' on one side and plain on the reverse. They come in blister packs of 30 and 90 tablets.

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Manufactured by 3M Health Care Ltd, 3M House, 1 Morley Street, Loughborough, Leicestershire, LE11 1EP, UK.

Procured from within the EU and repackaged by the Product Licence holder: O.P.D. Laboratories Ltd., Unit 6 Colonial Way, Watford, Herts WD24 4PR.

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PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Nefopam hydrochloride 30mg Tablets

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In this leaflet:

1. What Nefopam hydrochloride 30mg Tablets is and what it is used for
2. What you need to know before you take Nefopam hydrochloride 30mg Tablets
3. How to take Nefopam hydrochloride 30mg Tablets
4. Possible side effects
5. How to store Nefopam hydrochloride 30mg Tablets
6. Contents of the pack and other information

1. What Nefopam hydrochloride 30mg Tablets is and what it is used for

Nefopam hydrochloride 30mg 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 hydrochloride 30mg Tablets does not stop the pain from happening, but you will not be able to feel the pain as much.

Nefopam hydrochloride 30mg 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 hydrochloride 30mg 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 Tablets

Do not take Nefopam hydrochloride 30mg Tablets 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
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Driving and using machines

Nefopam hydrochloride 30mg Tablets can cause drowsiness. Do not drive or operate heavy machinery unless you know how Nefopam hydrochloride 30mg Tablets affects you.

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Dosage for adults:

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

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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 hydrochloride 30mg Tablets depending upon your condition.

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