

Package leaflet: Information for the patient

Azuzote 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.

What is in this leaflet

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1. What Azuzote Film-coated Tablets are and what they are used for

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

Azuzote 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). Azuzote Film-coated Tablets should not be used to treat the pain from a heart attack.

2. What you need to know before you take Azuzote Film-coated Tablets

Do not take Azuzote Film-coated 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
- 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)?

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

Other medicines and Azuzote Film-coated Tablets

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
- Tricyclic antidepressants for depression
- Anticholinergics
- Sympathomimetic.

Pregnancy and breast-feeding

Azuzote 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. Please contact your doctor if you become pregnant during your treatment.

Driving and using machines

Azuzote Film-coated Tablets can cause drowsiness. Do not drive or operate heavy machinery unless you know how Azuzote Film-coated Tablets affect you.

3. How to take Azuzote 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.

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.

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 adolescents and children:

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

Under 12 years - Azuzote 30 mg Film-coated Tablets should not be taken by children under 12.

Dosage for elderly 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 Azuzote Film-coated Tablets depending upon your condition.

If you take more Azuzote 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 Azuzote Film-coated Tablets

If you forget to take Azuzote Film-coated 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 Azuzote Film-coated Tablets

Do not stop taking Azuzote 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 Azuzote Film-coated 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).

Other side effects include:

Rare (may affect up to 1 in 1,000 people)

- becoming dependent on Azuzote (drug dependence).

Not known (frequency cannot be estimated from the available data)

- feeling sick
- feeling light-headed, dizzy or nervous, or fainting
- decrease in blood pressure
- numbness or tingling in the extremities
- dry mouth
- having difficulty passing urine
- convulsions, tremor
- confusion
- hallucinations (seeing things that aren't there)
- being sick
- abdominal pain or diarrhoea
- blurred vision
- drowsiness
- sweating
- trouble sleeping
- headaches
- awareness of your heartbeat (palpitations), or a fast heartbeat (tachycardia).

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: HPRA

Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Azuzote 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. The expiry date refers to the last day of that month.
- This medicine 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. These measures will help protect the environment.

6. Contents of the pack and other information

What Azuzote Film-coated Tablets contain

The active substance is nefopam hydrochloride. Each tablet contains 30 mg of nefopam hydrochloride. The other ingredients are:

Core tablet: microcrystalline cellulose (E460), calcium hydrogen phosphate dihydrate (E341), colloidal anhydrous silica, pregelatinised starch, hydrogenated vegetable oil, magnesium stearate.

Film-coating: hypromellose, titanium dioxide and macrogol.

What Azuzote Film-coated Tablets look like and contents of the pack

White to off-white coloured, round, bevel-edged, film-coated tablets debossed with 'N 30' on one side and plain on other side.

Azuzote 30 mg Film-coated Tablets are available in Alu-PVC blisters of 30 or 90 tablets.

Not all pack sizes may be marketed.

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