

PACKAGE LEAFLET: INFORMATION FOR THE USER

Alimemazine tartrate 10 mg film-coated tablets

alimemazine tartrate

Your medicine is called Alimemazine tartrate 10 mg film-coated tablets, but it will be referred to as Alimemazine tablets throughout this 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

What is in this leaflet

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1. What Alimemazine tablets are and what they are used for

Alimemazine tablets contain the active ingredient alimemazine tartrate and belongs to a group of medicines called phenothiazines. It works by blocking a natural substance (histamine) that your body makes during an allergic reaction. It also works directly on the brain to help you feel more relaxed.

What Alimemazine tablets are used for

- To treat itching (pruritus) or an itchy, lumpy rash (urticaria) in adults

2. What do you need to know before you take alimemazine tablets**Do not take this medicine and tell your doctor if:**

- You are allergic (hypersensitive) to:
 - alimemazine tartrate or any of the other ingredients of this medicine (listed in section 6)
 - any other similar medicines (phenothiazines) such as chlorpromazine

The signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue

- You have liver or kidney problems

- You have epilepsy
- You have Parkinson's disease (see "Other medicines and Alimemazine tablets")
- You have thyroid problems (hypothyroidism)
- You have a tumour on the adrenal gland (called pheochromocytoma)
- You have myasthenia gravis (a form of muscle weakness)
- You have an enlarged prostate gland
- You have increased pressure in the eye (called narrow angle glaucoma)
- You have a history of a blood or bone marrow disorder called agranulocytosis.

Children

Alimemazine tablets must not be used in children less than 3 years old.

Do not take this medicine if any of the above applies to you.

If you are not sure, talk to your doctor or pharmacist before taking Alimemazine tablets.

Warnings and precautions

Talk to your doctor or pharmacist before taking Alimemazine tablets if:

- You have heart problems
- You have fits (epilepsy)
- You are elderly and are dehydrated or have been told you have a low blood volume
- You are elderly and have had constipation for some time
- You are an elderly male and have problems when passing water (urinating)
- You are elderly and it is very hot or cold. Your body may find it harder to control its temperature when taking this medicine

Alimemazine tablets can make your skin more sensitive to sunlight. Keep out of direct sunlight while taking this medicine.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Alimemazine tablets.

Other medicines and Alimemazine tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you can buy without prescription, including herbal medicines. This is because Alimemazine tablets can affect the way some medicines work.

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In particular, tell your doctor or pharmacist if you are taking any of the following:

- Medicines to help you sleep or lower your anxiety
- Lithium – used to treat some types of mental illness
- Amphetamine – used for Attention Deficit Hyperactivity Disorder (ADHD)
- Phenobarbital – used for epilepsy
- Adrenaline – used for life threatening allergic reactions

- Medicines for Parkinson's disease such as levodopa (see "Do not take this medicine and tell your doctor if ")
- Medicines for depression
- Medicines for severe pain (such as codeine or morphine)
- Medicines for diabetes. Your doctor may need to change the dose of your medicine
- Medicines for high blood pressure such as doxazosin, terazosin, guanethidine or clonidine
- Medicines for indigestion and heartburn (antacids)
- Anticholinergic medicines – includes some medicines used for irritable bowel syndrome, asthma or incontinence

Alimemazine tablets with alcohol

Do not drink alcohol or take any medicines containing alcohol while you are taking Alimemazine tablets. This is because alcohol can increase the chances of you getting side effects. It can also cause serious breathing difficulties.

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should not take Alimemazine tablets if you are breast-feeding. This is because small amounts may pass into mothers' milk. This can be harmful to your baby.

If you are breast-feeding or planning to breast-feed, talk to your doctor or pharmacist before taking any medicine.

Driving and using machines

You may feel drowsy or sleepy while taking this medicine. If this happens, do not drive or use any tools or machines.

Alimemazine tablets contain lactose

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

3. How to take Alimemazine tablets

Always take this medicine exactly as your doctor has told you.

Check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth
- Do not touch the tablets for any longer than is necessary. This can cause skin redness, swelling and itching (contact skin sensitisation)
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor
- **Do not take more than the recommended dose**

How much to take

The usual dose is:

For itching or an itchy, lumpy rash

Adults:

- One tablet (10mg) two or three times each day

Elderly:

- One tablet (10mg) once or twice each day

If you take more alimemazine than you should

If you take more alimemazine than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken. Also do this if a child under 3 years of age swallows some of this medicine.

The following effects may happen: feeling drowsy, loss of consciousness, increased or rapid heartbeat, changes in heartbeat, uneven heart beats and feeling very cold. You may also feel dizzy, light-headed or faint (due to low blood pressure) and you may notice that you cannot control your movements (for example of the eyes, neck, arms and legs).

If you forget to take Alimemazine tablets

If you forget a dose, take it as soon as you remember it.

However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Alimemazine tablets and see a doctor or go to a hospital straight away if you notice any of the following side effects:

- An allergic reaction. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- Liver problems that may cause the eyes or skin to go yellow (jaundice)
- High temperature, sweating, stiff muscles, fast heartbeat, fast breathing and feel confused, drowsy or agitated. These could be signs of a serious side effect called 'neuroleptic malignant syndrome'
- Very fast, uneven or forceful heartbeat (palpitations). You may also have breathing problems such as wheezing, shortness of breath, tightness in the chest and chest pain
- Convulsions/fits and movements that you cannot control, mainly of the tongue, mouth, jaw, arms and legs
- You may get infections more easily than normal such as fever, severe chills, sore throat or mouth ulcers. These could be signs of a blood problem

Tell a pharmacist or doctor as soon as possible if you have any of the following side effects:

- Breathing more slowly or less deeply than normal
- Feeling restless and not being able to keep still
- Changes in skin or eye colour
- Problems with your eyesight
- Rigid or stiff muscles, trembling or shaking or difficulty moving
- Feeling dizzy, lightheaded or faint when you stand or sit up quickly (due to low blood pressure)

- Unexpected excitement or hyperactivity. Problems passing urine.

Tell your doctor or pharmacist if any of the following side effects gets serious or lasts longer than a few days or if you notice any side effects not listed in this leaflet:

- Constipation
- Dry mouth
- Stuffy nose
- Difficulty sleeping (insomnia)
- Feeling agitated
- Dizziness
- Headache
- Drowsiness
- Being more sensitive to the sun than usual
- Unusual production of breast milk in men and women
- Breast enlargement in men
- Loss of menstrual periods
- Difficulty in getting or maintaining an erection or in ejaculating (impotence)
- Skin redness, swelling and itching (contact skin sensitisation)
- Skin rashes

Reporting side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effect not listed in this leaflet.

You can also report side effects directly (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

Website: www.hpra.ie

5. How to store Alimemazine 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 after 'EXP'. The expiry date refers to the last day of that month.

This medicinal product 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.

If this medicine becomes discoloured or shows any other sign of deterioration, please contact your pharmacist who will advise you on what to do.

6. Contents of the pack and other information

What Alimemazine tablets contain

Each tablet contains 10mg of the active ingredient, alimemazine tartrate.

The other ingredients are lactose monohydrate, microcrystalline cellulose, sodium starch glycolate (Type A), colloidal anhydrous silica, magnesium stearate, hypromellose, macrogol 1500, lake indigo carmine (E132), talc, titanium dioxide (E171).

What Alimemazine tablets look like and contents of the pack

Blue, round, biconvex film-coated tablets, debossed with 'A' on one side and '1' on other side.

The tablets are available in aluminium/PVC/PVDC blister packs of 28 and 30. Not all pack sizes may be marketed.

Marketing Authorisation Holders:

UK: Key Pharmaceuticals Ltd.

Galen House, 83 High Street,

Somersham, Cambridgeshire,

PE28 3JB, UK

IE: Lexon Pharmaceuticals (Ireland) Limited

Block 4, Port Tunnel Business Park, Clonshaugh,

Dublin 17, Ireland

Manufacturer:

Noumed Life Sciences Limited

Noumed House, Shoppenhangers Road,

Maidenhead, Berkshire,

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