

PACKAGE LEAFLET: INFORMATION FOR THE USER

Alimemazine Tartrate 7.5 mg /5 ml Syrup
Alimemazine Tartrate 30 mg /5 ml Syrup

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

1. What Alimemazine is and what it is used for
2. What you need to know before you take Alimemazine
3. How to take Alimemazine
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1. WHAT ALIMEMAZINE IS AND WHAT IT IS USED FOR



The name of your medicine is Alimemazine Tartrate 7.5 mg/5 ml Syrup or Alimemazine 30 mg/5 ml Syrup (called alimemazine throughout this leaflet). It contains the active ingredient alimemazine tartrate and belongs to a group of medicines called phenothiazines and 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 is used for

- To treat itching (pruritus) or an itchy, lumpy rash (urticaria)
- As a sedative for children aged between 3 and 7 years. This is a medicine given to reduce awareness or make the child feel relaxed and at ease before an operation

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ALIMEMAZINE

Do not take alimemazine if:

- You are allergic (hypersensitive) to:
 - alimemazine tartrate or any of the other ingredients in 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.
- You have thyroid problems (hypothyroidism).
- You have a tumour on the adrenal gland (called phaeochromocytoma).
- 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 should 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.

Warnings and precautions

Talk to your doctor or pharmacist before taking alimemazine if:

- You are diabetic. This medicine contains sucrose, a type of sugar.
- 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.

of the recommended maximum daily dietary intake of sodium for an adult.

- The 30 mg/5 ml syrup contains 28 mg sodium (main component of cooking/table salt) in each 5 ml. This is equivalent to 1.4 % of the recommended maximum daily dietary intake of sodium for an adult.

3. HOW TO TAKE ALIMEMAZINE

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
- Avoid the syrup touching any part of your skin. 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

For itching or an itchy lumpy rash

Adults

- 10 mg two or three times each day.
- Your doctor may increase your dose depending on your illness.

Elderly

- 10 mg once or twice each day.

Children over 3 years of age

Alimemazine Tartrate 7.5mg/5ml Syrup should be used:

- 2.5 to 5 mg three or four times each day.

As a sedative before general anaesthesia

Children aged between 3 and 7 years

Alimemazine Tartrate 7.5mg/5ml Syrup should be used:

- Your child's doctor will decide the amount to give.
- The maximum dose is 2 mg per kg of bodyweight.
- Alimemazine is given 1-2 hours before the operation.

Exposure to sunlight

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

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 heart beat, 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

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 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 (akathisia).

- You are an elderly male and have problems when passing water (urine).
- You are elderly and it is very hot or cold. Your body may find it harder to control its temperature when 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.

Other medicines and alimemazine

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 can affect the way some medicines work. Also some medicines can affect the way alimemazine works.

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.
- 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, clonidine.
- Medicines for indigestion and heartburn (antacids).
- Anticholinergic medicines – includes some medicines used for irritable bowel syndrome, asthma or incontinence.

Alimemazine with alcohol

Do not drink alcohol or take any medicines containing alcohol while you are taking alimemazine. 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 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 Syrup contains sucrose, ethanol, sodium benzoate (E 211), sodium sulphite anhydrous (E 221), sodium metabisulphite (E 223) and sodium.

- This medicine contains 3.40 g of sucrose per 5ml. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. This should be taken into account in patients with diabetes mellitus.
- Sodium sulphite anhydrous (E 221) and sodium metabisulphite (E 223): These may rarely cause severe hypersensitivity reactions and bronchospasms.
- This medicine contains 5 mg of sodium benzoate (E211) in each 5ml dose.
- This medicine contains 203 mg alcohol (ethanol) in each 5ml. The amount in this medicine is equivalent to 5ml of beer or 2ml of wine per 5ml. The alcohol in this preparation is likely to affect children. These effects may include feeling sleepy and changes in behaviour. It may also affect their ability to concentrate and take part in physical activities. The amount of alcohol in this medicine can affect your ability to drive or use machines. This is because it may affect your judgement and how fast you react.

If you have epilepsy or liver problems, talk to your doctor or pharmacist before taking this medicine.

The amount of alcohol in this medicine may alter the effects of other medicines.

Talk to your doctor or pharmacist if you are taking other medicines. If you are pregnant or breastfeeding, talk to your doctor or pharmacist before taking this medicine.

If you are addicted to alcohol, talk to your doctor or pharmacist before taking this medicine.

- The 7.5 mg/5 ml syrup contains 31.7 mg sodium (main component of cooking/table salt) in each 5 ml. This is equivalent to 8.1 %

- Changes in skin or eye colour.
- Problems with your eyesight.
- Rigid or stiff muscles, trembling or shaking or difficulty moving.
- Feeling dizzy, light-headed 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 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. HOW TO STORE ALIMEMAZINE

- Keep out of the sight and reach of children.
- Do not use alimemazine after the expiry date which is stated on the carton and bottle label after EXP. The expiry date refers to the last day of that month.
- Do not use alimemazine after the bottle has been opened for more than a month.
- Store below 25°C.
- Protect from light.
- 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 Alimemazine contains

- Each 1ml of Alimemazine 7.5 mg/5 ml syrup contains 1.5mg of the active substance, alimemazine tartrate.
- Each 1 ml of Alimemazine 30 mg/5 ml syrup contains 6 mg of the active substance, alimemazine tartrate.
- The other ingredients are sucrose, apricot flavour (no. 1NS), ethanol, citric acid anhydrous, sodium citrate granules, sodium benzoate, sodium sulphite anhydrous, sodium metabisulphite powder, L (+) ascorbic acid and demineralised water. Alimemazine also contains caramel.

What Alimemazine syrup looks like and contents of the pack

Alimemazine Tartrate 7.5 mg/5 ml Syrup is a clear bright straw coloured syrupy liquid with a smell of apricots. It is available in glass bottles of 100 ml.

Alimemazine Tartrate 30 mg/5 ml Syrup is a clear colourless to very pale yellow syrupy liquid with a smell of apricots. It is available in glass bottles of 100ml.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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Manufacturer

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This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

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