

**ALIMEMAZINE TARTRATE 7.5MG/5ML & 30MG/5ML SYRUP**

Read all of this leaflet carefully before you start using 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 syrup is and what it is used for
2. What you need to know before you take Alimemazine syrup
3. How to take Alimemazine syrup
4. Possible side effects
5. How to store Alimemazine syrup
6. Contents of the pack and other information

1. WHAT ALIMEMAZINE SYRUP IS AND WHAT IT IS USED FOR

The name of your medicine is Alimemazine tartrate 7.5mg/5ml or 30mg/5ml Syrup (called Alimemazine syrup throughout this leaflet). This 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 syrup is used for:

- to treat itching (pruritus) or an itchy, lumpy rash (urticaria)
- as a sedative before anaesthesia for children aged between 2 and 7 years. This medicine is given to reduce awareness or make the child feel relaxed and at ease before an operation. (Alimemazine tartrate 30mg/5ml Syrup only).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ALIMEMAZINE SYRUP

Do not take Alimemazine syrup and tell your doctor if you:

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

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 syrup.

Warnings and Precautions

Talk to your doctor or pharmacist before taking Alimemazine syrup if you:

- are diabetic. This medicine contains sucrose, a type of sugar.
- have heart problems are elderly and are dehydrated or have been told you have a low blood volume
- are elderly and have had constipation for some time
- are an elderly male and have problems when passing water (urinating)
- are elderly and it is very hot or cold. Your body may find it harder to control its temperature when taking this medicine
- have seizures.

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

Children

- Alimemazine syrup must NOT be used in children less than 2 years old.
- Alimemazine Tartrate 30mg/5ml Syrup should NOT be used in children unless it is used as a sedative before anaesthesia for children aged between 2 and 7 years, to reduce awareness or make them feel relaxed and at ease before an operation.

Other medicines and Alimemazine syrup

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

This includes medicines you buy without a prescription, including herbal medicines. This is because Alimemazine syrup can affect the way in which some other medicines work. Also some medicines can affect the way Alimemazine syrup works.

Tell your doctor if you are taking any of the following:

- medicines to help you sleep or lower your anxiety
- lithium (to treat some types of mental illness)
- amphetamine (for Attention Deficit Hyperactivity Disorder (ADHD))
- phenobarbital (to treat epilepsy)
- adrenaline (to treat life-threatening allergic reactions)
- medicines for Parkinson's disease, such as levodopa (see "Do not take Alimemazine syrup")
- medicines for depression
- medicines for severe pain, such as codeine or morphine
- medicines for diabetes. Your doctor may need to change your 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 syrup with alcohol

Do NOT drink alcohol or take any medicines containing alcohol while you are taking Alimemazine syrup. 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 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.

You should NOT take Alimemazine syrup if you are breast-feeding. This is because small amounts may pass into the mother's milk. This can be harmful to your baby.

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.

Important information about some of the ingredients of Alimemazine syrup

This medicine contains :

- **Sucrose.** This is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine
- **Sodium sulphite (E221) and sodium metabisulphite (E223).** These may rarely cause severe allergic (hypersensitivity) reactions and difficulty breathing, wheezing and tightness in the chest (bronchospasm)
- **Ethanol.** Alimemazine Syrup contains 5% ethanol (alcohol) i.e. up to 81mg ethanol per 2ml dose. This is equivalent to 2ml beer and less than 1ml wine per dose. This can be harmful for those suffering from alcoholism. To be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease or epilepsy.
- **Sodium.** This medicine contains 24.36 mg sodium (main component of cooking/table salt) in each 5ml. This is equivalent to 1.17% of the recommended maximum daily dietary intake of sodium for an adult.

3. HOW TO TAKE ALIMEMAZINE SYRUP

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Taking this medicine

- Swallow this medicine. A 2 ml graduated dosing syringe and syringe adaptor are also provided for accurate dosing
- 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.

Instruction for proper use of the dosing pipette and adaptor

The adaptor is inserted in the bottle before use. The pipette is then put in the adaptor in the upright position and then turned upside down together with the bottle (Fig. 1). In this position the medicine is dosed. At the start of the measuring procedure, the transparent dosing body as well as the white plunger must be in the bottommost position. To measure the dosing

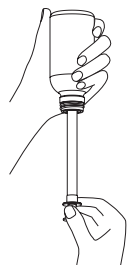


Fig. 1

quantity, use one hand to hold the bottom, transparent dosing body and the other hand to pull on the top, white plunger until you can read the desired quantity in ml.

Afterwards the bottle is turned in the upright position again and the dosed pipette can be removed (Fig. 2). The bottle is sealed after removing the inserted adaptor by using the common closure.



Fig. 2

The recommended dose is:

Alimemazine tartrate 30mg/5ml Syrup

For itching or an itchy, lumpy rash

- Adults:

- 10mg (approx. 1.6ml) two or three times each day.
Your doctor may increase your dose in some cases.

- Elderly:

- 10mg (approx. 1.6ml) once or twice each day.

Children less than 12 years:

Children less than 12 years of age should be prescribed Alimemazine syrup in a lower strength (7.5 mg/5 ml) syrup formulation for itching or an itchy, lumpy rash.

As a sedative before an operation

- Children aged between 2 and 7 years:

- Your child's doctor will decide the amount to give.
- The maximum dose is up to 2mg (approx. 0.33ml) per kg of bodyweight.
- Alimemazine syrup is given 1-2 hours before the operation.

Alimemazine tartrate 7.5mg/5ml Syrup

For itching or an itchy, lumpy rash

- Children over 2 years of age:

- Aged 2 to 5: 2.5mg (1.7ml) of Alimemazine syrup should be used three to four times per day
- Aged 5 to 12: 5mg (3.3ml) of Alimemazine syrup should be used three to four times per day.

As a sedative before an operation

- Children aged between 2 and 7 years:

- For the indication of sedation prior to anaesthesia, which requires a once only, high dose of Alimemazine syrup, the higher strength (30mg/5ml) syrup should be prescribed in order to limit ethanol exposure.

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 syrup than you should

If you take more Alimemazine syrup than you should, tell a doctor or go to a hospital casualty department **immediately**. Take the medicine pack with you. This is so the doctor knows what you have taken. Also do this if a child under 2 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 heartbeats and feeling very cold. You may also feel dizzy, light-headed or faint (due to low blood pressure) and you may notice you cannot control your movements (for example of the eyes, neck, arms and legs).

If you forget to take Alimemazine syrup

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 medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Alimemazine syrup can cause side effects, although not everybody gets them.

Stop taking Alimemazine syrup 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, rigid or stiff muscles, fast heartbeat, fast breathing and feeling 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 a sign of blood problems.

Tell your doctor or pharmacist straight away 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)
- changes in skin or eye colour
- problems with your eyesight
- 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
- difficulty in emptying the bowels (constipation)
- difficulty in passing urine.

Tell your doctor or pharmacist if any of the following side effects get serious or last longer than a few days:

- dry mouth/stuffy nose
- difficulty sleeping (insomnia)
- feeling agitated
- 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, and itching (contact skin sensitisation).

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. (See details below)

United Kingdom: 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 SYRUP

Keep out of the sight and reach of children.

- Do not use this medicine after the expiry date, which is stated on the carton and bottle label after EXP. The expiry date refers to the last day of the month.
- Do not use after the bottle has been opened for more than a month.
- Do not use if the product appears to have deteriorated, such as if there are changes in colour of the solution or if the solution becomes cloudy or hazy.
- Store in the original package in order to protect from light.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Alimemazine syrup contains

- Each 1ml of Alimemazine 7.5mg/5ml syrup contains 1.5mg of the active substance, Alimemazine tartrate.
- Each 1ml of Alimemazine 30mg/5ml syrup contains 6mg of the active substance, Alimemazine tartrate.
- The other ingredients are sucrose, ethanol, citric acid monohydrate anhydrous (E330), sodium benzoate (E211), sodium sulphite anhydrous (E221), sodium metabisulphite (E223), ascorbic acid (E300), apricot flavour, caramel flavour and sodium citrate (E331).

What Alimemazine syrup looks like and contents of the pack

Alimemazine tartrate 7.5mg/5ml syrup is a clear colourless to pale yellow syrupy liquid. It is available in glass bottles of 100ml.

Alimemazine tartrate 30mg/5ml syrup is a clear colourless to pale yellow syrupy liquid. It is available in amber glass bottles of 100ml.

A 2 ml graduated dosing syringe and syringe adaptor are also provided.

Marketing Authorisation Holder

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