Alimemazine tartrate 7.5mg/5ml oral solution, sugar-free

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 your 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 use Alimemazine
3. How to take Alimemazine
4. Possible side effects
5. How to store Alimemazine
6. Contents of the pack and other information

1. What Alimemazine is and what it is used for

The name of your medicine is Alimemazine tartrate 7.5mg/5ml oral solution, sugar-free (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 2 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 this medicine and tell your doctor if
- You are allergic (hypersensitive) to:
  - alimemazine tartrate or any of the other ingredients in this medicine (listed in section 6 below)
  - 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 2 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 have heart problems
- 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 (urine)
- You have fits (epilepsy)
- 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 or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist 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 contains sodium sulphite, sodium metabisulphite, sodium benzoate, sodium, propylene glycol and ethanol
- **Sodium sulphite and sodium metabisulphite:** These may rarely cause severe hypersensitivity reactions and bronchospasm.
- **Sodium benzoate:** This medicine contains 5.0 mg sodium benzoate in 5 ml oral solution.
- **Sodium:** This medicine contains less than 1 mmol sodium (23mg) per dosage, that is to say essentially 'sodium-free'. Take this into account if you are on a controlled sodium diet.
- **Propylene glycol:** This medicine contains 253.3 mg propylene glycol in 5 ml oral solution.
- **Ethanol:** This medicinal product contains small amounts of ethanol (alcohol), less than 100 mg per 5 ml.

3. How to take Alimemazine

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

Taking this medicine
- Take this medicine by mouth
- Avoid the medicine 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
The usual dose is:
Alimemazine tartrate 7.5mg/5ml oral solution, sugar-free

For itching or an itchy lumpy rash
Adults:
- 10 mg (approx. 6.7 ml) two or three times daily.
- Your doctor may increase your dose depending on your illness.

Older people
- 10 mg (approx. 6.7 ml) once or twice daily.

Children
- 2-5 years of age: 2.5 mg (approx. 1.7 ml) three or four times daily.
- 5-12 years of age: 5 mg (approx. 3.4 ml) three or four times daily.

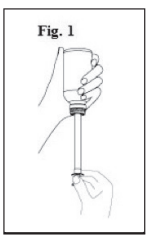
Continued overleaf

- Over 12 years of age: 10 mg (approx. 6.7 ml) two or three times daily.

As a sedative before anaesthesia
- For the indication of sedation prior to anaesthesia, which requires a once only, high dose of alimemazine, the higher strength 30mg/5ml oral solution should be prescribed in order to limit propylene glycol (excipient) exposure.

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

Instructions on how to take Alimemazine:



The adaptor is inserted in the bottle before use. The syringe 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 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 syringe can be removed (Fig. 2).
The bottle is sealed after removing the inserted adaptor by using the common closure.

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 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 heartbeat 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 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 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)
- 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:
- 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, swelling and itching (contact skin sensitisation)
- Skin rashes
- Constipation, dizziness, headache, drowsiness.

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: Yellow Card Scheme Website: 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.

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 tartrate 7.5mg/5ml oral solution, sugar-free contains 1.5mg of the active substance, alimemazine tartrate.
- The other ingredients are propylene glycol (E1520), sodium benzoate (E211), citric acid monohydrate (E330), sodium citrate dehydrate (E331), sodium metabisulfite (E223), sodium sulphite (E221), ascorbic acid (E300), sodium cyclamate (E952), peach flavour, hydrochloric acid (for pH-adjustment) (E507) and purified water.

What Alimemazine looks like and contents of the pack
Alimemazine tartrate 7.5mg/5ml oral solution is a clear colourless to pale yellow liquid, with peach odour.

Alimemazine tartrate 7.5mg/5ml oral solution is packed in a 100ml glass bottle with a child resistant screw cap and comes with a syringe adaptor and a graduated 0.1mL dosing syringe of 5mL

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