

## Alimemazine tartrate 7.5 mg/ 5 ml oral solution, Sugar-Free Alimemazine tartrate 30 mg/ 5ml oral solution, Sugar-Free

alimemazine tartrate

**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).

The name of your product is Alimemazine tartrate 7.5 mg/ 5 ml or 30 mg/ 5 ml oral solution Sugar-Free, but it will be referred to as Alimemazine oral solution throughout this leaflet.

### What is in this leaflet

1. What Alimemazine oral solution is and what it is used for
2. What you need to know before you take Alimemazine oral solution
3. How to take Alimemazine oral solution
4. Possible side effects
5. How to store Alimemazine oral solution
6. Contents of the pack and other information

### 1. What Alimemazine oral solution is and what it is used for

The name of your medicine is Alimemazine oral solution, Sugar-Free (called Alimemazine oral solution throughout this leaflet). Alimemazine oral solution 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.

This medicine is used:

- 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 oral solution

**Do not take Alimemazine oral solution 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.
- 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.
- The patient is a child 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 oral solution.

### Warnings and precautions

Talk to your doctor or pharmacist before taking Alimemazine oral solution 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 (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.

### Exposure to sunlight

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

### Children

Alimemazine oral solution should not be used in children less than 2 years old.

### Other medicines and Alimemazine oral solution

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 oral solution can affect the way some medicines work. Also some medicines can affect the way Alimemazine oral solution 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.
- Amfetamine - 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 oral solution with alcohol

Do not drink alcohol or take any medicines containing alcohol while you are taking this medicine. 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.

Do not take this medicine if you are breast-feeding. This is because small amounts may pass into mother's 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 oral solution contains sodium methyl parahydroxybenzoate

This medicine contains sodium methyl parahydroxybenzoate and may cause allergic reactions (possibly delayed).

This medicine contains less than 1 mmol sodium (23 mg) per 10 ml dose (for Alimemazine 7.5 mg/ 5 ml oral solution) and per 8.5 ml dose (for Alimemazine 30 mg/ 5ml oral solution), that is to say essentially 'sodium-free'.

### 3. How to take Alimemazine oral solution

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 oral solution 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.

### Dosage

#### For itching or an itchy lumpy rash

#### Adults

- 10 mg (approx. 1.6 ml of Alimemazine 30 mg/ 5 ml oral solution or approx. 6.5 ml of Alimemazine 7.5 mg/ 5 ml oral solution) two or three times each day.
- Your doctor may increase your dose depending on your illness.

#### Elderly

- 10 mg (approx. 1.6 ml of Alimemazine 30 mg/ 5 ml oral solution or approx. 6.5 ml of Alimemazine 7.5 mg/ 5 ml oral solution) once or twice each day.

#### Children over 2 years old

- 2.5 - 5 mg (approx. 1.7 - 3.3 ml of Alimemazine 7.5 mg/ 5 ml oral solution) three or four times each day.

#### As a sedative

#### Children between 2 and 7 years old

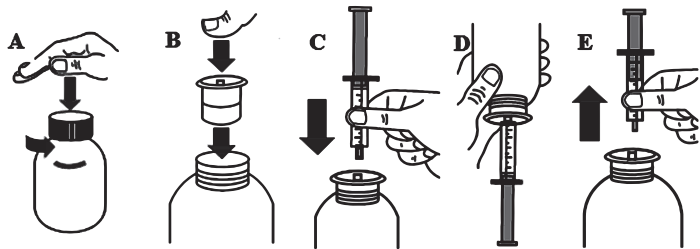
- Your child's doctor will decide the amount to give.
- The maximum dose is 2 mg (approx. 1.3 ml of Alimemazine 7.5 mg/ 5 ml oral solution) per kg of bodyweight.
- This medicine is given 1-2 hours before the operation.

## Method of administration

For oral administration.

A 5 ml graduated oral syringe with intermediate graduations of 0.1 ml and a "Press-In" Bottle Adapter (PIBA) are provided with the product.

1. Open the bottle and at first use insert the "Press-In" Bottle Adapter (PIBA) (see pictures A-B).
2. Insert the syringe into the PIBA and draw out the required volume from the inverted bottle (see pictures C-D).
3. Remove the filled syringe from the bottle in the upright position (see picture E).
4. Discharge the syringe contents into the mouth. Repeat steps 2 to 4 as needed to achieve the required dose.
5. Rinse the syringe and replace the cap on the bottle (PIBA remains in place).



### If you take more Alimemazine oral solution than you should

If you take more of this medicine 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 heartbeats and feeling very cold. You may also feel dizzy, lightheaded 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 oral solution

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 oral solution 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 your doctor or pharmacist 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:**

- 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 Website: [www.mhra.gov.uk/yellowcard](http://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 oral solution

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 label after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light.

### After first opening use within 1 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 oral solution contains

The active substance is alimemazine tartrate.

- Each 5 ml of Alimemazine 7.5 mg/ 5 ml oral solution contains 7.5 mg alimemazine tartrate.
- Each 5 ml of Alimemazine 30 mg/ 5 ml oral solution contains 30 mg alimemazine tartrate.

The other ingredients are sodium methyl parahydroxybenzoate (E 219), sucralose (E 955), hydrochloric acid, concentrated (for pH adjustment) and purified water.

### What Alimemazine oral solution looks like and contents of the pack

Alimemazine oral solution is a clear, colourless to yellowish solution. It is supplied in a 100 ml amber type III glass bottle, safely closed with a child-resistant screw cap with tamper evident closure.

A 5 ml graduated oral syringe with intermediate graduations of 0.1 ml and a "press-in" syringe/bottle adapter are also provided.

### Marketing Authorisation Holder

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### Manufacturer

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