## PACKAGE LEAFLET: INFORMATION FOR THE USER

# ALIMEMAZINE TARTRATE 10MG FILM-COATED TABLETS

# 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 tablets are and what they are used for
- 2. What you need to know before you take Alimemazine tablets
- 3. How to take Alimemazine tablets
- 4. Possible side effects
- 5. How to store Alimemazine tablets
- 6. Contents of the pack and other information

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

The name of your medicine is Alimemazine tartrate 10mg film-coated tablets (called Alimemazine tablets 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 tablets are used for:

- to treat itching (pruritus) or an itchy, lumpy rash (urticaria)
- as a sedative 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. (The use of Alimemazine syrup is recommended for this indication).

## 2. What you need to know before you take Alimemazine tablets

## Do not take Alimemazine tablets 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")
- have thyroid problems (hypothyroidism)
- have a tumour on the adrenal gland (called phaeochromocytoma)
- have myasthenia gravis (a form of muscle weakness)
- have an enlarged prostate gland

- have increased pressure in the eye (called narrow angle glaucoma).

- You 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 tablets.

## Warnings and Precautions

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

- 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 tablets.

#### Children

Alimemazine tablets 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 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 buy without a prescription, including herbal medicines. This is because Alimemazine tablets can affect the way in which some other medicines work. Also some medicines can affect the way Alimemazine tablets 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")
- 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 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 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 tablets 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.

## Alimemazine tablets contains lactose

Alimemazine tablets contains lactose (a sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Alimemazine tablets.

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

## 3. How to take Alimemazine tablets

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

- Swallow this medicine.
- Do not touch the tablets for 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.

## The recommended dose is:

## For itching or an itchy, lumpy rash

- Adults:

• One tablet (10mg) two or three times each day. Your doctor may increase your dose in some cases.

## - Elderly:

• One tablet (10mg) once or twice each day.

## - Children over 2 years of age:

o Children will normally be given Alimemazine syrup. Check with your doctor or pharmacist.

## As a sedative

## - Children aged between 2 and 7 years:

• The use of Alimemazine syrup is recommended for children in this indication. Check with your doctor or pharmacist.

## Exposure to sunlight

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

## If you take more Alimemazine tablets than you should

If you think that you, or any other person, may have taken too many tablets, contact a doctor or hospital casualty department **immediately**. Take any remaining tablets and this leaflet so the medical staff knows exactly what you/they 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 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 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 medicine, ask your doctor or pharmacist.

## 4. Possible side effects

Like all medicines, Alimemazine tablets 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, 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
- 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.
- problems with passing urine.

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

- 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)

## **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 affects you can help provide more information on the safety of this medicine.

#### 5. How to store Alimemazine tablets

#### 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 blister. The expiry date refers to the last day of the month.

Do not store above 30°C. 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 tablets contains

The active substance is Alimemazine tartrate. Each tablet contains 10mg of Alimemazine tartrate.

The other ingredients are lactose monohydrate, microcrystalline cellulose, magnesium stearate, colloidal anhydrous silica, sodium starch glycolate, hypromellose, macrogoll 400, blue opaspray M-1-4229 (purified water, indigo carmine, titanium dioxide, industrial methylated spirits 74).

#### What Alimemazine tablets look like and contents of the pack

Alimemazine tablets are dark blue, circular, biconvex and film-coated tablets. One side is marked with AL and the other side is plain. They are supplied in packs of 28 tablets.

## **Marketing Authorisation Holder**

Mercury Pharmaceuticals Ltd, Dashwood House, 69 Old Broad Street, London, EC2M 1QS, United Kingdom

#### Manufacturer

Mercury Pharmaceuticals Limited Capital House, 85 King William Street, London EC4N 7BL, United Kingdom

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