

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 symptoms 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 medicine is Alfredes 7.5mg/5ml Syrup, but it will be referred to as Alfredes throughout this leaflet.

What is in this leaflet:

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

1. What Alfredes is and what it is used for

Alfredes contains the active substance alimemazine tartrate and it 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 Alfredes 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 Alfredes

Do not take Alfredes and tell your doctor 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

- ▶ have liver or kidney problems
- ▶ have epilepsy
- ▶ have Parkinson’s disease
- ▶ 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).

Children

Alfredes should not be used in children under 2 years of age.

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 Alfredes.

Warnings and precautions

Talk to your doctor or pharmacist before taking Alfredes if:

- ▶ the person taking the medicine is under 2 years of age
- ▶ you are diabetic. This medicine contains sucrose, a type of sugar
- ▶ 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 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 Alfredes.

Other medicines and Alfredes

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 Alfredes can

affect the way some medicines work. Also some medicines can affect the way Alfredes 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.

Alfredes with alcohol

Do not drink alcohol or take any medicines containing alcohol while you are taking Alfredes. 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 planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should not take Alfredes if you are breastfeeding. 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.

Alfredes contains

Sucrose: If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. Furthermore, sucrose may be harmful to the teeth if this medicine is taken for long-term use e.g. for two weeks or more.

Methyl parahydroxybenzoate (E218), which may cause allergic reactions (possibly delayed).

Sodium sulfite anhydrous (E221) and sodium metabisulfite (E223): These may rarely cause severe hypersensitivity reactions and difficulty breathing, wheezing and tightness in the chest (bronchospasm).

This medicine contains less than 1 mmol **sodium** (23 mg) per 5ml, that is to say essentially ‘sodium-free’.

3. How to take Alfredes

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

How much to take

The recommended dose is:

For itching or an itchy lumpy rash

Adults:

- ▶ 10mg (approx. 6.7ml of syrup) two or three times each day
- ▶ Your doctor may increase your dose depending on your illness.

Older people:

- ▶ 10mg (approx. 6.7ml of syrup) once or twice each day.

Children over 2 years of age:

- ▶ 2.5 to 5mg (approx. 1.7ml to 3.3ml of syrup) three or four times each day.

As a sedative

Children aged between 2 and 7 years:

- ▶ Your child’s doctor will decide the amount to give
- ▶ The maximum dose is 2mg (approx. 1.3ml of syrup) per kg of bodyweight
- ▶ Alfredes is given 1-2 hours before the operation.
- ▶ Alfredes syrup of a higher strength (30mg/5ml) is recommended if a smaller volume of syrup for administration is required.

Exposure to sunlight

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

When 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
- ▶ Use the measuring syringe provided in the pack to deliver the required dose.

Instructions for the use of syringe:

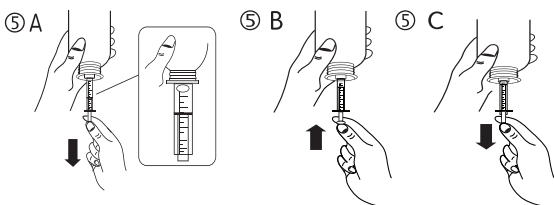
1. Open the bottle: press the cap and turn it anticlockwise (figure 1). Separate the adaptor from the syringe (figure 2).



2. Insert the adaptor into the bottle neck (figure 3). Ensure it is properly fixed. Take the syringe and put it in the adaptor opening (figure 4).



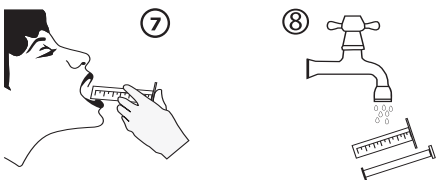
3. Turn the bottle upside down. Fill the syringe with a small amount of syrup by pulling the piston down (figure 5A), then push the piston upwards in order to remove any possible bubble (figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (figure 5C).



4. Turn the bottle the right way up (figure 6A). Remove the syringe from the adaptor (figure 6B).



5. Empty the contents of the syringe into the patient's mouth by pushing the piston to the bottom of the syringe (figure 7). Leave the syringe adaptor in place after first use. Close the bottle with the plastic screw cap. Wash the syringe with water (figure 8).



If you take more Alfresed than you should

If you take more Alfresed 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 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 Alfresed

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, this medicine can cause side effects, although not everybody gets them.

Stop taking Alfresed 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)
- ▶ 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.

Tell your doctor or pharmacist if any of the following side effects gets serious or lasts 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, 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 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 Alfresed

- ▶ Keep this medicine out of the sight and reach of children.
- ▶ Do not take this medicine after the expiry date, which is marked on the carton and bottle label after EXP. The expiry date refers to the last day of that month.
- ▶ This medicine does not require any special storage conditions.
- ▶ Discard this medicine 30 days after first opening.
- ▶ Do not use this medicine if you notice that the syrup appears to have deteriorated, such as changes in colour of the syrup or if the syrup becomes cloudy or hazy. Seek the advice of your pharmacist.
- ▶ 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 Alfresed contains

The active substance is alimemazine tartrate.

Each 5ml of syrup contains 7.5mg alimemazine tartrate.

The other ingredients are sucrose, citric acid monohydrate, sodium citrate, methyl parahydroxybenzoate (E218), sodium sulfite anhydrous (E221), sodium metabisulfite (E223), ascorbic acid, caramel flavour, apricot flavour and purified water.

What Alfresed looks like and contents of the pack

Alfresed is a clear, colourless to pale yellow syrupy liquid with caramel odour supplied in an amber glass bottle of 100ml, with a tamper evident, child resistant white plastic cap and a 5ml oral syringe with 0.1ml graduation and a syringe adaptor.

Marketing Authorisation Holder and Manufacturer:

SyriMed,
Unit 4, Bradfield Road,
Ruislip, Middlesex,
HA4 0NU, UK.

If this leaflet is hard to see or read, please call +44 (0) 208 515 3700 for help.

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