



Package Leaflet: Information for the User

ACTIFED Syrup

Pseudoephedrine hydrochloride 30 mg and Triprolidine hydrochloride 1.25 mg/5ml Oral Solution

ATTENTION

Actifed Syrup is authorised for use without the need of a medical prescription in Adults and Children over 12 years as recommended by your pharmacist. In Children between 2-11 years of age, this product is authorised for use only against a medical prescription as recommended by your doctor.

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/recommended for you or your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same.
- If you or your child 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 Actifed Syrup is and what it is used for
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1 What Actifed Syrup is and what it is used for

Actifed Syrup contains 30 mg Pseudoephedrine hydrochloride and 1.25 mg Triprolidine hydrochloride (the active ingredients) in each 5 ml dose. There are also some inactive ingredients in Actifed Syrup.

Actifed Syrup is for the relief of symptoms of cold, flu and hay fever. Pseudoephedrine hydrochloride is a decongestant, which means it acts to relieve blocked noses and sinuses. Triprolidine hydrochloride is an antihistamine, which means it will help stop sneezing, watering and soreness in the nose and eyes.

2 What you need to know before you use Actifed Syrup

Do not use Actifed Syrup:

- If your child is less than 2 years old.

- If you or your child are allergic (hypersensitive) to Pseudoephedrine hydrochloride, Triprolidine hydrochloride or any of the other ingredients of Actifed Syrup (listed in Section 6).
- If you or your child suffered or suffer from severe kidney disease.
- If you or your child have high blood pressure or heart disease.
- If you or your child are taking or have you recently taken any of the following:
 - Prescribed medicine for the treatment of depression, particularly those belonging to the group called monoamine oxidase inhibitors (MAOI's)
 - Any other medicine for a blocked or runny nose
 - Prescribed medicine for the treatment of high blood pressure
 - Appetite suppressants (medicines which stop you feeling hungry)
 - Any medicine that makes you feel drowsy, such as antihistamines.

Do not use if any of the above apply to you or your child. If you are not sure, talk to your doctor or pharmacist before using Actifed Syrup.

Warnings and precautions

- Talk to your doctor or pharmacist before using Actifed Syrup:
 - If you or your child have been told you have diabetes, hyperthyroidism, glaucoma (increased fluid pressure in the eye) or an enlarged prostate.
 - If you or your child suffer from phaeochromocytoma, epilepsy (fits) or liver disease.
 - If you or your child have a persistent or chronic cough such as occurs with asthma, smoking or emphysema.
 - If you or your child are or could be pregnant or breast feeding.
- Talk to your doctor or pharmacist while using Actifed Syrup:
 - If you or your child experience sudden abdominal pain or blood in the stools.
 - If you or your child experience sudden severe headache.
- Avoid drinking alcohol whilst taking Actifed Syrup.
- Make sure your doctor/pharmacist knows what other medicines are being taken, including those that may have been bought without medical prescription.
- Do not use any other medicines that contain pseudoephedrine or triprolidine whilst taking Actifed Syrup, if you are unsure ask your doctor or pharmacist.
- Actifed Syrup may cause drowsiness or difficulty in concentration. Do not drive or operate machinery until you have determined whether Actifed Syrup makes you drowsy or causes a lack of concentration.
- Children and the elderly are more prone to side effects.

3 How to use Actifed Syrup

If you have any difficulties or do not understand the instructions ask your doctor or pharmacist.

Ensure the medicine is taken as your doctor/pharmacist has told you. The label on it will usually tell you how much to take and how often. If you are not sure ask your doctor or pharmacist.

USE OF ACTIFED SYRUP WITHOUT MEDICAL PRESCRIPTION

This product is authorised for use without a medical prescription (over-the-counter) as recommended by your pharmacist for the following:

Adults (including the elderly) and Children over 12 years of age

The usual dose of Actifed Syrup is:

Adults and children over 12 years 10ml every 4 to 6 hours, up to 4 times a day.

USE OF ACTIFED SYRUP AGAINST MEDICAL PRESCRIPTION

This product is authorised for use against a medical prescription (prescription-only) as recommended by your doctor for the following:

Children 2 years to 11 years of age

The usual dose of Actifed Syrup is:

Children aged 6 to 11 years 5ml every 4 to 6 hours, up to 4 times a day

Children aged 2 to 5 years 2.5ml every 4 to 6 hours, up to 4 times a day.

- Actifed Syrup is not suitable for children aged less than 2 years.
- Actifed Syrup is not suitable for administration to children aged under 6 years, except on the advice of your doctor.
- The bottle should be shaken thoroughly before use.
- Do not use more than the recommended amount shown above.
- If the symptoms (cough and cold) do not improve after a few days, talk to your doctor.

If you use more Actifed Syrup than you should

It is important that the amount recommended by your doctor/pharmacist as shown above, is taken.

If you or your child accidentally swallow too much Actifed Syrup, tell your doctor straight away, even if you or your child feel OK. If you cannot see your doctor, go straight to the accident and emergency unit of your nearest hospital. Take the medicine with you to help the hospital staff identify what has been taken.

If you forget to use Actifed Syrup

If a dose is forgotten, do not worry; take the next dose and another 4 to 6 hours later and so on. Just remember, no more than four doses should be taken in a day.

4 Possible side effects

Most people taking this medicine find that it causes no problems. As with all medicines a few people may find that it causes side effects.

Stop using Actifed Syrup and tell your doctor immediately if:

You experience allergic reactions with any of the following symptoms soon after taking Actifed Syrup: skin rashes or irritation, sometimes with breathing problems or swelling of the face and/or throat. These reactions are rare.

Other side effects you may notice when using Actifed Syrup include:

- Sleep disturbances and hallucinations.
- Dryness of the mouth, nose or throat.
- Difficulty in passing water (this is more likely in men).
- Faster than usual heart beats.
- Nervousness and dizziness.

If any other symptoms are experienced that you do not understand, tell your doctor or pharmacist.

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 national reporting system:

ADR Reporting

Website: www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Actifed Syrup

- Do not use after the date shown as “Exp” on the carton and label.
- Keep your Actifed Syrup where children cannot see or reach it. It may harm them.
- Store at room temperature (below 25 °C) with the lid tightly closed and in the original container.
- Do not throw away 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 Actifed Syrup contains

- The active ingredients are Pseudoephedrine hydrochloride 30 mg and Triprolidine hydrochloride 1.25 mg/5ml oral solution.
- The other ingredients are syrup BP, methyl hydroxybenzoate, sodium benzoate, glycerol, E104, E110, sodium hydroxide and purified water.

What Actifed Syrup looks like and contents of the pack

Within each carton is a glass bottle with an aluminium cap, which contains 100 ml of oral solution.

Marketing Authorisation Holder and Manufacturer

GlaxoSmithKline (Ireland) Ltd, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland hold the product licence.

Actifed Syrup is made by Aspen Bad Oldesloe GmbH, Industriestrasse 32-36, D-23843 Bad Oldesloe, Germany.

If you have any questions or are not sure about anything, ask your doctor or pharmacist who will advise you.

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