

ACTIFED[®] SYRUP

Pseudoephedrine hydrochloride/Tripolidine hydrochloride (30 mg/1.25 mg per 5 ml)

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What ACTIFED is used for

ACTIFED syrup is a medicine which is used to relieve the symptoms of upper respiratory tract disorders such as allergic rhinitis (inflammation of the mucous membrane inside the nose), vasomotor (non-allergic) rhinitis, common flu and influenza including sneezing, runny nose, watery eyes, nasal congestion and blocked sinuses.

How ACTIFED works

ACTIFED contains pseudoephedrine hydrochloride, which is a decongestant that works by narrowing the blood vessels to decrease swelling and nasal congestion and tripolidine hydrochloride which is an antihistamine that works by blocking a certain natural substance (histamine) that your body makes during an allergic reaction.

Before you use ACTIFED

- When you must not use it

Do not use this medicine if:

- You are allergic to pseudoephedrine, tripolidine, or any of the other ingredients.
- You have very high blood pressure or severe heart disease
- You are taking, or have taken in the last two weeks,

medicines for depression known as Monoamine Oxidase Inhibitors (MAOIs).

- You are taking antihistamine-containing products
- You are taking other medicines for the relief of coughs, colds or flu, congestion or blocked nose;

- Before you start to use it

Talk to your doctor or pharmacist if you:

- Have liver or kidney problems
- Have high blood pressure or heart disease
- Have an irregular heartbeat
- Have diabetes or if you been told by your doctor that you have an intolerance to some sugars.
- Have an overactive thyroid gland.
- Have glaucoma (increased pressure in the eye)
- Have prostate problems (difficulty with passing water or needing to pass water often)
- Have epilepsy or asthma
- Have bronchitis (inflammation of the airway) or bronchiectasis (airways of the lungs become abnormally widened)
- Phaeochromocytoma (a rare tumor of adrenal gland located above the kidneys

Ask your doctor or pharmacist for advice before taking this medicine if you are pregnant or breast-feeding.

- Taking other medicines

Talk to your doctor or pharmacist if you are taking any other medicines, including:

- Sedatives (medicines used to treat anxiety and tension).
- Antihypertensives (medicines used to treat high blood

pressure such as guanethidine, methyl dopa, alpha and beta blockers and debrisoquine).

- Sympathomimetic medicines (stimulants or appetite suppressants and medicines used to treat congestion and asthma).

If you are not sure about any of the medicines you are taking, show the bottle or pack to your pharmacist.

How to use ACTIFED

- How much to use

Adults and children age 12 years and above:

- 10 ml syrup, every 4-6 hours, to be taken orally.
Maximum daily dose: 40ml syrup in any 24 hours

Children aged 6 to 11 years:

- 5 ml syrup every 4-6 hours, to be taken orally.
- Maximum daily dose: 20ml syrup in any 24 hours

Children aged 2 to 5 years:

- 2.5 ml syrup every 4-6 hours, to be taken orally.
- Maximum daily dose: 10ml syrup in any 24 hours

Not to be used in children less than 2 years of age. To be used with caution on doctor's/pharmacist's advice in children 2 to 6 years of age.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking ACTIFED for as long as your doctor recommends. Please seek

medical advice if symptoms persist for more than 7 days.

- If you forget to use it

If you forget to take a dose, take the next dose when needed provided that the last dose was taken at least 4 hours ago. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Pseudoephedrine overdose may result in symptoms due to central nervous system and cardiovascular stimulation (e.g. excitement, restlessness, hallucinations, high blood pressure and irregular heartbeats. In severe cases, psychosis, convulsions, coma and severe increase in blood pressure may occur.

Low blood potassium may also occur.

Tripolidine overdose is likely to result in effects similar to those listed under adverse reactions. Additional symptoms may include lack of coordination, weakness, decreased ability to exhale and inhale, dryness of the skin and mucous membranes, exceptionally high fever, tremor, psychosis, convulsions, abnormally rapid heart rate and irregular heartbeats.

While you are using it

- Things you must do

Check with your doctor or pharmacist before taking your medicine and take it as prescribed by your doctor.

Tell all the doctors, dentists and pharmacists treating you that you are taking ACTIFED.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

Do not exceed the frequency of dosing.

- Things to be careful of

This medicine may affect your ability to drive or operate machinery and it may cause drowsiness, dizziness and blurred vision. If affected, do not drive or operate machinery. Avoid alcoholic drink.

ACTIFED contains 3.93 g of sucrose per 5 ml. This should be taken into account if you have diabetes mellitus.

Children and the elderly are more prone to adverse events.

Side Effects

ACTIFED can have side-effects, like all medicines, although these do not affect everyone and are usually mild.

When using this product you may experience:

- Sedation and drowsiness which are very common.
- Nervousness, difficulty sleeping, dizziness, dry

mouth, nose or throat, nausea, vomiting, disturbance in attention and abnormal co-ordination which may occasionally occur.

- Hallucinations (particularly in children) which have been reported rarely.

Stop using this product and consult your doctor if you experience:

- Sudden abdominal pain or blood in your stools.
- Sudden severe headache.
- Difficulty in passing water. This is more likely to occur if you have an enlarged prostate gland.
- Allergic reactions such as skin rash, sometimes with breathing problems or swelling of the face and/or throat. These reactions are rare.

If you experience any side effects not included in this leaflet or are not sure about anything, talk to your doctor or pharmacist.

You may report any side effects of adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

Storage and Disposal of ACTIFED

- Storage

Store below 25°C. Store in the original package to protect from light and moisture. Keep the product out of the reach and sight of children. Do not use after the end of the month shown as an expiry date on the packaging.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment

Product Description

- What it looks like

Actifed syrup is available in bottle of 100ml.

- Ingredients

- Active ingredient(s)

1.25 mg triprolidine hydrochloride and 30 mg pseudoephedrine hydrochloride in each 5 ml.

- Inactive ingredient(s)

Syrup, quinoline yellow E104, purified water, glycerol, sodium benzoate, sunset yellow E110, sodium hydroxide, methyl parahydroxybenzoate.

- MAL number

MAL19860257ACZ

Manufacturer

Aspen Bad Oldesloe GMBH
Industriestrasse 32-36,
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Product Registration Holder

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