ACTIFED® EXPECTORANT

Pseudoephedrine Hydrochloride/ Triprolidine Hydrocholoride/Guaiphenesin (30 mg/1.25 mg/100 mg per 5ml)

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What ACTIFED EXPECTORANT is used for

Actifed Expectorant is indicated for the symptomatic relief of upper respiratory tract disorders accompanied by productive cough, which benefit from the administration of a nasal decongestant, a histamine H1-receptor antagonist and an expectorant combination.

How ACTIFED EXPECTORANT works

The liquid contains pseudoephedrine hydrochloride, which is a decongestant that relieves nasal and sinus congestion, triprolidine hydrochloride which is an antihistamine that helps stop sneezing, runny nose and watery eyes and guaifenesin, which is an expectorant that helps to loosen the mucus in your throat and chest.

Before you use ACTIFED EXPECTORANT

- When you must not use it

Do not use if:

 You are allergic to pseudoephedrine, triprolidine, guaiphesin or any of the other ingredients.

- You have serious kidney problems, unless your doctor tells you to.
- You have serious high blood pressure or heart disease.
- You are taking any other medicines for the relief of coughs, cold or flu, congestion or blocked nose
- You are taking antihistamines
- You are taking any appetite suppressants or stimulant medicines called amphetamines (e.g. sometimes used to treat attention deficit disorders).
- You are taking or have taken in the past two weeks, medicines called monoamine oxidase inhibitors (MAOI's).

If any of these apply to you, get advice from a doctor or pharmacist before taking Actifed Expectorant.

- Before you start to use it

Check with your doctor before use if:

- You have an overactive thyroid gland, fits, prostate gland enlargement, an irregular heartbeat, glaucoma (excessive pressure inside your eyes), diabetes, asthma, moderate kidney impairment, respiratory inflammation or phaeochromocytoma (tumour of adrenal gland)
- You have serious liver problems.
- You are taking medicines to control your blood pressure e.g. medicines called beta-blockers
- You are pregnant or breastfeeding
- You have rare hereditary sugar intolerance problems

Each 5ml spoonful of this medicine contains 0.35ml of alcohol (ethanol). If you suffer from alcoholism, epilepsy (fits) or

liver disease, speak to your doctor before taking this medicine.

- 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, methyldopa, beta blockers, debrisoquine and betanidine).
- Sympathomimetic medicines (stimulants or appetite suppressants and medicines used to treat nose 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 EXPECTORANT

- How much to use

Adults and children aged 12 years and over:

- Usual dose: 10 ml taken every 4-6 hours as required
- Maximum daily dose: 40 ml oral solution in 24 hours

Children 6 to 11 years of age:

- Usual dose: 5 ml oral solution taken every 4-6 hours as required
- Maximum daily dose: 20 ml oral solution in 24 hours

Children 2 to 5 years of age:

- Usual dose: 2.5 ml oral solution taken every 4-6 hours as required
- Maximum daily dose: 10 ml syrup in 24 hours
- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

To be taken every 4-6 hours as required. Continue taking Actifed Expectorant for as long as your doctor recommends.

- If you forget to use it

If you forget to take a dose, take the next dose when needed. Do not take a double dose

- If you use too much (overdose)

If you take too much medicine: seek medical advice immediately

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.

Triprolidine overdose is likely to result in effects similar to those listed under side effects.

Additional symptoms may include lack of movement coordination, weakness, breathing difficulty, dryness of the skin and mucous membranes, exceptionally high fever, tremor, psychosis, convulsions, abnormally rapid heart rate and irregular heartbeats.

Guaiphenesin overdose may result in nausea and vomiting.

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.

- 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 drink alcohol whilst using this medicine.

- Things to be careful of

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

This product may cause dizziness, drowsiness or blurred vision. You should not drive or operate machinery until you are sure you are not affected.

Actifed Expectorant contains sucrose. This should be taken into account if you have diabetes.

Actifed Expectorant should not be used for persistent or chronic cough such as occurs with smoking, asthma or emphysema (chronic lung disease) or where cough is accompanied by excessive secretion unless directed by a physician.

Actifed Expectorant contains methyl parahydroxybenzoate and colouring, which may cause allergic reactions (possibly delayed).

If you have sudden onset of abdominal pain and rectal bleeding, seek medical advice and Actifed Expectorant should be discontinued immediately

If you develop sudden onset of severe headache, nausea, vomiting and visual disturbances, seek medical advice and Actifed Expectorant should be discontinued immediately

Side Effects

Like all medicines, Actifed Expectorant can cause side effects, although not everybody gets them. Visit your pharmacist immediately if you experience any side effects after taking this medicine.

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 coordination which may commonly occur
- Hallucinations (hearing voices or seeing things which are not there, particularly in children) which have been reported rarely.

Children and the elderly are more likely to experience side effects.

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

- Difficulty in passing urine. This is more likely to occur if you have an enlarged prostate gland
- Allergic reactions such as skin rash, itching, swelling (sometimes of the face, mouth or throat causing difficulty in breathing) and collapse. These reactions are rare.

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 EXPECTORANT

- Storage

Keep the product out of the reach and sight of children. Store below 25°C and protect from light Do not refrigerate

- 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

A clear, orange-coloured, spicy lemon-flavoured oral solution

- Ingredients
 - Active ingredient(s)

30 mg Pseudoephedrine Hydrocholoride, 1.25 mg Triprolidine Hydrocholoride, and 100 mg Guaiphenesin in each 5 ml

Inactive ingredient(s)

Sorbitol 70%, syrup, methyl parahydroxybenzoate, sodium benzoate, levomenthol, suset yellow E110/FD&C Yellow No 6, Ethanol, Spicy Lemon FC900853, purified water.

- MAL number

MAL19860308ACZ

Manufacturer

Aspen Bad Oldesloe GMBH Industriestrasse 32 – 36, 23843, Bad Oldesloe, Germany

Product Registration Holder

GlaxoSmithKline Pharmaceutical Sdn Bhd, Level 6, Quill 9, 112 Jalan Semangat, 46300 Petaling Jaya, Selangor, Malaysia

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