



Actifed®

30 mg / 1.25 mg per 5 ml Syrup

Pseudoephedrine hydrochloride
Triprolidine hydrochloride

- This medicine is used to relieve the symptoms of colds and allergies including runny nose, watery eyes, nasal congestion, blocked sinuses and catarrh.
- This medicine is for use by adults and children aged 6 years and over.
- **Do not use this medicine:**
 - If you have an **overactive thyroid gland**.
 - If you have **glaucoma** (increased pressure in the eye).
 - If you have **prostate problems** (difficulty with passing water or needing to pass water often).
 - There are some people who should not use this medicine. *To find out if you are one of them See Section 2 ▶*
 - If you have ever had a **bad reaction** to any of the ingredients. *For the list of ingredients See Section 6 ▶*
- **Speak to your doctor:**
 - If you suffer from any of the conditions mentioned in Section 2. *See Section 2 ▶*
 - If you are taking any **other medicines**. *See Section 2 ▶*
- **Follow the dosage instructions carefully.** Children of different ages and adults need different amounts. These are shown in the tables. *See Section 3 ▶*

Now read this whole leaflet carefully before you use this medicine. Keep the leaflet: you might need it again.

What the medicine is for

Actifed Syrup is a medicine which is used to relieve the symptoms of colds and allergies including sneezing, runny nose, watery eyes, nasal congestion and blocked sinuses. The liquid contains pseudoephedrine hydrochloride, which is a decongestant that relieves nasal and sinus congestion and triprolidine hydrochloride which is an antihistamine that helps stop sneezing, runny nose and watery eyes.

This medicine is for use in adults and children aged 6 years and over.

2 Before taking this medicine

This medicine is suitable for most adults and children aged 6 years and over but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist.

X Do not take this medicine...

- If you have ever had a **bad reaction (allergic reaction)** to any of the ingredients (For a list of ingredients see section 6).
- If you have **high blood pressure** or **heart disease**.
- If you are taking, or have taken in the last two weeks, **drugs for depression** known as Monoamine Oxidase Inhibitors (MAOIs).
- If you are taking **furazolidone** (an antibacterial agent).
- If you are taking any other cough and cold medicines.
- If you have an **overactive thyroid gland**.
- If you have **glaucoma** (increased pressure in the eye).
- If you have **prostate problems** (difficulty with passing water or needing to pass water often).

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

⚠ Talk to your doctor or pharmacist...

- If you have **liver** or **kidney problems**.
- If you have **diabetes** or have been diagnosed with an **intolerance to some sugars**.
- If you are taking **alcohol**.
- If you have **epilepsy**.
- If you are taking any **other medicines**, including:
 - **Sedatives and tranquilizers** (drugs used to treat **anxiety and tension**).
 - **Antihypertensives** (drugs used to treat **high blood pressure** such as *bretium, bethanidine, guanethidine, debrisoquine, methyl dopa, alpha- and beta-adrenergic block agents*).
 - **Sympathomimetic drugs** (stimulants or appetite suppressants and drugs used to treat congestion and asthma).
 - **Tricyclic antidepressants** (used to treat **mood disorders**).
 - **Anticholinergics** drugs such as atropine.

- **Monoaminoxidase inhibitors (MAOIs)** (used to treat **depression**).
- If you have a respiratory condition such as emphysema (shortness of breath, with a cough), chronic bronchitis, or acute or chronic bronchial asthma.

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

If any of these bullet points apply to you now or in the past, **talk to a doctor or pharmacist.**

⚠ If you are pregnant or breast-feeding

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

⚠ Special warnings about this medicine

- This medicine may cause drowsiness. If affected, do not drive or operate machinery. **Avoid alcoholic drink.**

⚠ Some of the ingredients can cause problems

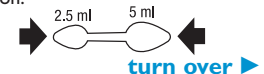
- Each 5 ml of this medicine contains 3.5 g of sucrose. This should be taken into account in patients with diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
- Methyl hydroxybenzoate (E218) may cause allergic reactions such as skin rash; this may happen after a few days.
- The colouring in this medicine (**sunset yellow (E110)**) may cause allergic reactions.

3 How to take this medicine

Check the tables below to see how much medicine to take.

- For oral use only.
- Always **shake the bottle** thoroughly before use.
- Do not use more than the stated dose shown in the table.
- Do not overfill the spoon.

There is a double-ended



spoon in the pack.

i Children under 6 years old

This medicine is not recommended for children under 6 years old.

i Children 6 - 12 years

Age	Dose
Children 6 – 12 years	One 5 ml spoonful every 4 - 6 hours, up to 3 times a day. Maximum daily dose: 15 ml.

- Leave at least 4 hours between doses.
- Do not give more than 3 doses in 24 hours.
- Use only when simple measures have failed to provide adequate relief.
- Do not use for more than 5 days without consulting your doctor or pharmacist.

i Adults and children over 12 years

Age	Dose
Adults and children over 12 years old	Two 5 ml spoonfuls every 4 - 6 hours, up to 4 times a day. Maximum daily dose: 40 ml.

- Leave at least 4 hours between doses.
- Do not give more than 4 doses in 24 hours.
- If symptoms persist talk to your doctor.

Elderly	Two 5 ml spoonfuls every 4 - 6 hours, up to 4 times a day. Maximum daily dose: 40 ml.
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- Leave at least 4 hours between doses.
- Do not give more than 4 doses in 24 hours.
- If symptoms persist talk to your doctor.
- Elderly patients should advise their doctor they are taking this medicine as their doctor may wish to monitor their kidney and liver function.
- Elderly patients with severe kidney or liver problems should talk to their doctor before taking this medicine. These patients should exercise caution when taking this product.

A If anyone has too much

If anyone has too much contact a doctor or your nearest Accident and Emergency Department taking this leaflet and pack with you.

A If you forget to take the medicine

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.

4 Possible side-effects

Like all medicines, Actifed Syrup can have side-effects, although these don't affect everyone and are usually mild.

If you experience any of the following, stop using this medicine and talk to your doctor:

- A few people have had hallucinations, but this is rare.
- Occasionally people get skin rashes that are sometimes itchy.
- A few people may find their heartbeat increased.
- A few men, especially men with prostate problems, may have trouble passing water.

Other effects which may occur include:

- Common (affects less than 1 in 10 but 1 or more in 100 people)
 - Inability to sleep
 - Nervousness
 - Dizziness
 - Dry mouth
 - Nausea (Feeling sick)
- Side effects for which frequency cannot be estimated from available data:
 - Feeling anxious
 - Euphoric mood
 - Restlessness
 - Epilepsy
 - Headache
 - Tingling or numbness of the hands or feet
 - Psychomotor hyperactivity (in the paediatric population)
 - Tremors
 - Drowsiness
 - Changes in the way the heart beats
 - Fast or irregular heartbeats
 - Dry throat
 - Bleeding from the nose
 - Nasal dryness
 - Abdominal discomfort
 - Vomiting
 - Itching
 - Itchy rash
 - Pain when passing urine
 - Feeling jittery
 - Fatigue
 - Blood pressure increased.

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

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 via HPRa Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2; Tel: +35316764971; Fax: +35316762517

Website: www.hpra.ie; Email: medsafety@hpra.ie.

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

5 Storing this medicine

Do not store above 25°C.

Keep out of the sight and reach of children.

Store in original container. Keep the bottle tightly closed.

Do not use after the expiry date stated as 'EXP' on the label and carton. The expiry date refers to the last day of that month.

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 protect the environment.

6 Further information

What's in this medicine?

The active ingredients in Actifed Syrup are:

Pseudoephedrine hydrochloride 30 mg and triprolidine hydrochloride 1.25 mg in each 5 ml spoonful.

Other ingredients are: Sucrose, glycerol, methyl hydroxybenzoate (E218), sodium benzoate (E211) quinoline yellow (E104), sunset yellow (E110) and purified water.

What the medicine looks like

Actifed Syrup is a clear yellow liquid available in 100 ml bottles.

Product Authorisation holder: McNeil Healthcare (Ireland) Ltd., Airton Road, Tallaght, Dublin 24, Ireland.

Manufacturer: Famar Orleans, 5 avenue de Concy, 45071 Orléans, Cedex 2, France

This leaflet was revised December 2014.

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McNeil
Healthcare (Ireland) Ltd.

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