

# ACTIFED® 60mg/2.5mg Tablets

Pseudoephedrine hydrochloride  
Triprolidine hydrochloride

- This medicine is used to relieve the symptoms of colds, flu and allergies including runny nose, watery eyes, nasal congestion and blocked sinuses.
- This medicine is for use by adults and children aged 12 years and over.
- **Do not use this medicine:**
  - 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 or pharmacist:**
  - 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.** 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 Tablets is a medicine which is used to relieve the symptoms of colds, flu and allergies including sneezing, runny nose, watery eyes, nasal congestion and blocked sinuses. The tablets contain 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 over 12 years.

## 2 Before taking this medicine

This medicine is suitable for most adults and children aged over 12 years but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist.

### 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 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 you have **very high blood pressure** or **severe 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 other sympathomimetic drugs (stimulants or appetite suppressants and drugs used to treat **congestion** and **asthma**).

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

### Talk to your doctor or pharmacist...

- If you have **liver** or **kidney problems**.
- If you have **high blood pressure** or **heart disease**.
- If you have **diabetes** or if you been told by your doctor that you have 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 *guanethidine, reserpine, methyldopa, alpha and beta blockers, debrisoquine, bretylium* and *betanidine*).
    - **Tricyclic antidepressants** (used to treat **mood disorders**).
    - **Halogenated anaesthetics agents** (such as *chloroform, cyclopropane, halothane, enflurane* or *isoflurane*).
  - 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, reduce alertness and impair hearing. If affected do not drive or operate machinery.

### Some of the ingredients can cause problems

- This medicine contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

turn over ▶

## 3 How to take this medicine

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

- For oral use only.
- Do not use more than the stated dose shown in the table.

### Children aged 12 years or under

This medicine is not recommended for children aged 12 years or under.

### Adults and children over 12 years

Age	Dose
Adults and children over 12 years old	One tablet every 4 - 6 hours, up to 4 times a day

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

### If anyone has too much

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

### 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 Tablets 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.

- Tremors, epilepsy.
- High fever.
- 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
- Headache
- Tingling or numbness of the hands or feet
- Psychomotor hyperactivity (in the paediatric population)
- Drowsiness
- Changes in the way the heart beats
- Palpitations
- Dry throat
- Bleeding from the nose
- Nasal dryness
- Abdominal discomfort
- Vomiting
- Itching
- Itchy rash
- Pain when passing urine
- Feeling jittery
- Fatigue
- Increased blood pressure

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 HPRC Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517 Website: www.hpra.ie; Email: mdsafety@hpra.ie.

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

## 5 Storing this medicine

Keep out of the sight and reach of children.

Do not use Actifed Tablets after the expiry date which is stated on the carton label and blister after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 25°C.

Store in original container to protect from moisture and light.

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.

## 6 Further information

### What's in this medicine?

**The active ingredients in Actifed Tablets are:** Pseudoephedrine hydrochloride 60 mg and triprolidine hydrochloride 2.5 mg in each tablet.

**Other ingredients are:** Lactose monohydrate, maize starch, povidone and magnesium stearate (E572).

### What the medicine looks like

Actifed Tablets are off-white, biconvex, branded and scored tablets, coded M2A available in packs of 12 tablets.

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

**Manufacturer:** Janssen Cilag, Domaine de Maigremont, 27100 Val de Reuil, France.

**This leaflet was revised December 2014.** Actifed is a registered trade mark.

**McNeil**  
Healthcare (Ireland) Ltd.

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