

Package leaflet: Information for the user

Actifed

60 mg / 2.5 mg Tablets

Pseudoephedrine hydrochloride

Triprolidine hydrochloride

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 5 days

What is in this leaflet

1. What Actifed Tablets is and what it is used for
2. What you need to know before you use Actifed Tablets
3. How to use Actifed Tablets
4. Possible side effects
5. How to store Actifed Tablets
6. Contents of the pack and other information

1. What Actifed Tablets is and what it is used 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 12 years and over.

2. What you need to know before you use Actifed Tablets

This medicine is suitable for most adults and children aged 12 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 use this medicine...

- If you have ever had a **bad reaction (allergic reaction)** to any of the ingredients (*listed in section 6*).
- If you have **diabetes**
- 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 a **phaeochromocytoma** (rare tumour that affects your heart rate and blood pressure)
- If you have **high blood pressure (hypertension) or hypertension not controlled by your medication or heart disease.**
- If you have **severe acute (sudden) or chronic (long-term) kidney disease or kidney failure.**
- If you have **lung disease or breathing difficulties.**
- If you are taking *beta blockers* (used to treat **high blood pressure**)
- If you are taking, or have taken in the last two weeks, **drugs for depression** known as Monoamine Oxidase Inhibitors (MAOIs) or Reversible Inhibitors of Monoamine Oxidase (RIMAs).
- If you are taking any **other cough and cold medicines**

If any of these apply to you, **get advice from a doctor or pharmacist without using Actifed Tablets.**

! Warnings and precautions

Talk to your doctor or pharmacist...

- If you have **kidney or severe liver problems.**
- If you are **susceptible to glaucoma** (increased pressure in the eye)
- If you have **blocked arteries or veins** (occlusive vascular disease).
- If you are being treated for a **thyroid disorder**
- If you have difficulty in passing water or need to pass water often (for example, due to prostate problems, or infection or inflammation of the bladder or urinary tract).
- If you have **alcohol dependence.**
- If you have **epilepsy.**

If you experience the following, stop taking the product immediately and contact your doctor:

- A feverish generalised erythema associated with pustules (see section 4)
- Sudden abdominal pain or rectal bleeding may occur with Actifed Tablets, due to inflammation of the colon (ischemic colitis). If you develop these gastro-intestinal symptoms, stop taking Actifed Tablets, and contact your doctor or seek medical attention immediately. See section 4.
- Cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) have been reported following use of medicines containing pseudoephedrine. PRES and RCVS are rare conditions that can involve reduced blood supply to the brain. Stop using Benylin Day & Night Tablets immediately and seek immediate medical assistance if you develop symptoms that may be signs of PRES or RCVS (see section 4 “Possible side effects” for symptoms)
- Sudden severe headaches, nausea, vomiting, confusion, fits, visual disturbances.

■ Reduction of blood flow to your optic nerve may occur with Actifed Tablets. If you develop sudden loss of vision, stop taking Actifed Tablets and contact your doctor or seek medical attention immediately. See section 4.

! Children

■ Do not use to sedate a child

! Other medicines and Actifed Syrup

Tell your doctor or pharmacist if you are taking any **other medicines**, including:

- *Sedatives* (drugs used to treat **anxiety** and **tension**).
- *Antihypertensives* (drugs used to treat **high blood pressure** such as guanethidine, reserpine, *methyl dopa*, *adrenergic neurone blockers*, *debrisoquine*, *bretylum* and *betanidine*).
- *Stimulants* or *appetite suppressants* and drugs used to treat **congestion** and **asthma** (*sympathomimetic drugs*).
- *Tricyclic antidepressants* (used to treat **mood disorders**).
- *Moclobemide* (used to treat **mood disorders**).
- *Cardiac glycosides* (drugs used to **control heart rhythms** or **contractions** such as digoxin).
- *Ergot alkaloids* (drugs used to treat **migraine** such as ergotamine and methysergide).
- *Oxytocin* (drugs used to help **contractions** during childbirth).
- *Anticholinergic drugs* (drugs used to treat **cramps** or **spasms** such as atropine)
- *Hypnotics* (**sleeping tablets** including barbiturates)
- *Opioid analgesics* (drugs used to **relieve pain** e.g. codeine, tramadol, morphine)
- *Antipsychotics* (drugs used to treat **mood disorders**)

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**.

! Pregnancy and breast-feeding

■ If you are pregnant, or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machine

■ This medicine may cause dizziness, drowsiness, reduce alertness and impair hearing. If affected, do not drive or operate machinery. **Avoid alcoholic drink.**

! Anti-doping tests

■ This medicine contains pseudoephedrine hydrochloride, which may produce positive results in anti-doping tests.

! Actifed Tablets 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.

3. How to use Actifed Tablets

Check the tables that follow to see how much medicine to take.

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

I Children under 12 years

This medicine should not be given to children under 12 years old

i Adults and children aged 12 years and over

Age	Dose
Adults and children aged 12 years and over	One tablet every 4-6 hours, up to 4 times a day.
<ul style="list-style-type: none">■ 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 or pharmacist	

! If you use more Actifed Tablets than you should

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

! If you forget to use Actifed Tablets

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 not everybody gets them.

If you experience any of the following, stop taking this medicine and seek immediate medical help:

- Stop using Actifed Tablets immediately and seek urgent medical attention if you develop symptoms, that may be signs of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS). These include:
severe headache with a sudden onset, feeling sick, vomiting, confusion, seizures changes in vision.
- Sudden onset of fever, reddening of the skin, or many small pustules (possible symptoms of Acute Generalized Exanthematous Pustulosis – AGEP) may occur within the first 2 days of treatment with this medicine (See section 2).
- Sudden stomach pains, passing blood in your stools or bleeding from your back passage and diarrhoea.

- Severe headache, nausea, vomiting, confusion, fits, visual disturbances.
- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.
- Feeling unusually tired, unexpected bruising or bleeding and getting more infections (such as colds) than normal.
- Allergic reactions including skin rashes such as hives (which may be severe and include blistering or peeling of the skin) and itching.
- Hallucinations, paranoid delusions or fits

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

- Restlessness or sleep disturbances
- A fast or irregular heartbeat or an increased awareness of the heartbeat (palpitations)
- Trouble passing water (especially in men with prostate problems)
- Reduced blood flow to the optic nerve (Ischaemic optic neuropathy)

Other effects which may occur include:

Very common (may affect more than 1 in 10 people)

- Headache

Common (may affect up to 1 in 10 people)

- Difficulty sleeping, nervousness, dizziness or feeling jittery
- Drowsiness
- Blurred vision
- Thickened mucus, dry mouth, nausea or an upset stomach

Rare (may affect up to 1 in 1000 people)

- Confusion or depression
- Tremor, shakiness or slurred speech
- Low blood pressure

Other effects which may occur but it is not known how often

- Serious conditions affecting blood vessels in the brain known as posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS)
- Stroke
- Heart attack/reduced blood flow to the heart which can cause discomfort or pain in the chest, neck, back, jaw, shoulders or arms (known as angina).
- Agitation, anxiety, irritability or feelings of extreme happiness
- Tingling or numbness of the hands or feet (pins and needles)
- High blood pressure
- Nose bleeds, dry nose or dry throat
- Vomiting or stomach discomfort
- Pain when passing water

- Inflammation of the colon due to insufficient blood supply (ischemic colitis)
- Feeling tired
- Very high fever

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, Website: www.hpra.ie.

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

5. How to store Actifed Tablets

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 protect the environment.

6. Contents of the pack and other information

What Actifed Tablets contain

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 Actifed Tablets looks like and the contents of the pack

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

Marketing Authorisation holder: JNTL Consumer Health I (Ireland) Ltd. Block 5, High Street, Tallaght, Dublin 24, Ireland

Manufacturer: JNTL Consumer Health (France) SAS, Domaine de Maigremont, 27100 Val de Reuil, France

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