

## Package leaflet: Information for the user

**Actifed**  
30 mg / 1.25 mg per 5 ml Syrup  
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 Syrup is and what it is used for

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

3. How to use Actifed Syrup

4. Possible side-effects

5. How to store Actifed Syrup

6. Contents of the pack and other information

## 1 What Actifed Syrup is and what it is used 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 What you need to know before you use Actifed Syrup

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 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 **high blood pressure (hypertension) or hypertension not controlled by your medication or heart disease**.

■ 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 you have **lung disease or breathing problems**.

■ If you have **diabetes**.

■ If you have **severe acute (sudden) or chronic (long-term) kidney disease or kidney failure**.

■ If you have an **overactive thyroid gland**.

■ If you have **glaucoma** (increased pressure in the eye).

■ 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 a **pheochromocytoma** (rare tumour which affects your heart rate and blood pressure).

If any of these applies, **get advice from a doctor or pharmacist without using Actifed Syrup**.

### ! 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 **prostate problems** (difficulty with passing water or needing to pass water often)

■ 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 Syrup, due to inflammation of the colon (ischemic colitis). If you develop these gastro-intestinal symptoms, stop taking Actifed Syrup, 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 Benlyn 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 Syrup. If you develop sudden loss of vision, stop taking Actifed Syrup and contact your doctor or seek medical attention immediately (*see section 4*).

### Children

■ Do not use to sedate a child.

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

### ! Other medicines and Actifed Syrup

**Tell your doctor or pharmacist if your child is taking any other medicines including:**

■ *Sedatives* (drugs used to treat **anxiety and tension**)

■ *Antihypertensives* (drugs used to treat **high blood pressure**, such as *bretylum, betanidine, guanethidine, reserpine, debrisoquine, methyl dopa, adrenergic neurone blockers*)

■ *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** e.g. digoxin).

■ *Ergot alkaloids* (drugs used to treat **migraine** such as ergotamine and methysergide).

■ *Oxytocin* (drug 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 treat **relieve pain** e.g. codeine, tramadol, morphine)

■ *Antipsychotics* (drugs used to treat **mood disorders**)

If you are not sure about the medicine your child is taking, show the bottle or pack to your pharmacist.

If any of these bullet points apply, **talk to a doctor or pharmacist**.

### ! Pregnancy and Breastfeeding

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

### ! Driving and using machines

■ This medicine may cause dizziness, drowsiness, reduce alertness and impair hearing. Avoid alcoholic drink.

### ! Anti-doping tests

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

### ! Actifed Syrup contains sucrose, methyl parahydroxybenzoate, sodium, sodium benzoate and sunset yellow

■ Each 5 ml of this medicine contains 3.5 g of sucrose. This should be taken into account in patients with diabetes mellitus.

■ Methyl hydroxybenzoate (E218) may cause allergic reactions such as skin rash; this may occur after a few days.

■ The colouring in this medicine (**sunset yellow E110**) may cause allergic reactions.

■ This medicine contains less than 1 mmol sodium (23 mg) per 5 ml, that is to say essentially 'sodium-free'.

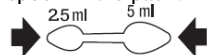
■ This medicine contains 5mg sodium benzoate (E211) in each 5ml dose.

## 3 How to use Actifed Syrup

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

- For oral use only
- Always **shake the bottle** thoroughly before use
- Do not take more than the stated dose shown in the table
- Do not use to sedate a child
- Do not overfill the spoon

There is a double-ended spoon in the pack.



### ! Children under 6 years

This medicine should not be given to children under 6 years old.

### ! Children 6 – 12 years

Age	Dose
<b>Children 6 – 12 years</b>	<b>One 5 ml spoonful</b> 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.	

### ! Adults and children aged 12 years and over

Age	Dose
<b>Adults and children aged 12 years and over</b>	<b>Two 5 ml spoonfuls</b> 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 or worsen talk to your doctor or pharmacist.	

### ! If you use more Actifed Syrup than you should

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

### If you forget use Actifed Syrup

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 not everybody gets them.

### ! If you experience the following stop using this medicine and seek immediate 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.

■ Allergic reaction including skin rashes such as hives (which may be severe and include blistering and peeling of the skin) and itching.

■ Hallucinations, paranoid delusions or fits.

### ! If you experience 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 your heartbeat (palpitations).

■ Trouble passing water (especially 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 unknown 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

- Inflammation of the colon due to insufficient blood supply (ischaemic colitis)
- Vomiting or stomach discomfort
- Pain when passing urine
- Feeling tired
- Very high fever

Actifed is a registered trademark

### 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](http://www.hpra.ie). By reporting side-effects you can help provide more information on the safety of this medicine.

## 5 How to store Actifed Syrup

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 Contents of the pack and other information

### What Actifed Syrup contains

#### The active ingredients in Actifed Syrup are:

Pseudoephedrine hydrochloride 30 mg and triprolidine hydrochloride 1.25mg per 5 ml.

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

### What the medicine like and the contents of the pack

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

#### The Marketing Authorisation holder:

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

#### Manufacturer:

Delpharm Orleans, 5 avenue de Concyr, 45071 Orléans, Cedex 2, France.

**This leaflet was revised**