

PACKAGE LEAFLET

Multi-Action ACTIFED® Dry Coughs

pseudoephedrine, triprolidine, dextromethorphan

- This medicine is used to help relieve symptoms of cold and flu including irritating dry cough and related congestion symptoms.
- 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:**
 - 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.

1 What the medicine is for

Multi-Action Actifed Dry Coughs is a medicine which is used to help relieve dry coughs and related congestion symptoms. The liquid contains triprolidine hydrochloride which is an antihistamine that helps stop sneezing, runny nose and watery eyes, pseudoephedrine hydrochloride which is a decongestant that unblocks stuffy noses and dextromethorphan hydrobromide which is an antitussive to help stop coughing.

The medicine is for use in adults and children aged 12 years and over.

2 Before taking this medicine

This medicine is suitable for most people but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist. This medicine can lead to dependence. Therefore the treatment should be of short duration.

X Do not use this medicine...

- If you have ever had a **bad reaction** to pseudoephedrine, triprolidine, dextromethorphan or any of the other ingredients.
- If you suffer from **lung disease**.

- If you have **diabetes**
- If you have a **phaeochromocytoma** (a rare tumour that affects your heart rate and blood pressure)
- If you have an **overactive thyroid gland**
- If you have **glaucoma** (increased pressure in the eye)
- If you have **severe kidney problems**
- If you have **high blood pressure** 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 *selective serotonin reuptake inhibitors* (used to treat **depression** and **anxiety** such as *fluoxetine*, *paroxetine* and *sertraline*)
- For children under 12 years old.

If any of these apply to you, **get advice from a doctor or pharmacist without using Multi-Action Actifed Dry Coughs.**

! Talk to your doctor or pharmacist...

- If you have **kidney** or **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 have **bronchitis**, **emphysema** or **asthma** or have had a **cough for a few weeks** or a **cough with a lot of mucus (phlegm)**.
- If you are being treated for a **thyroid disorder**
- If you have difficulty passing water or **prostate problems** (which may mean you need to pass water more often).
- If you are or have ever been addicted to opioids, alcohol, prescriptions medicines, or illegal drugs.
- If you have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- If you have been told by your doctor that you are a **slow metabolizer of CYP2D6**.
- If you are taking medicines such as certain antidepressants or antipsychotics this medicine may interact with these medicines and you may experience mental status changes (e.g. agitation, hallucinations, coma), and other effects such as body temperature above 38°C, increase in heart rate, unstable blood pressure, and exaggeration of reflexes, muscular rigidity, lack of coordination and/or gastrointestinal symptoms (e.g. nausea, vomiting, diarrhoea).
- If you are taking any other **cough and cold medicines**.
- If your child is prone to developing certain allergic reactions (e.g. **atopic reactions**)
- If you are taking any **other medicines**, including:
 - *Sedatives* (drugs used to treat **anxiety** and **tension**).
 - *Hypnotics* (**sleeping tablets** including barbiturates)

- Certain **drugs for depression** such as norepinephrine-dopamine reuptake inhibitors (NDRIs), which include bupropion
- *Tricyclic antidepressants* (used to treat **mood disorders**).
- *Sympathomimetic drugs* (*stimulants* or *appetite suppressants* or drugs used to treat **congestion** and **asthma**).
- *Anticholinergic drugs* (drugs used to treat **cramps** and **spasms** such as *atropine*)
- *Antihypertensives* (drugs used to treat **high blood pressure** such as *guanethidine*, *methyl dopa*, *adrenergic neurone blockers*, *debrisoquine*, *bretylum* and *betanidine*).
- *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* (drug used to help **contractions during childbirth**)
- *Antipsychotics* (drugs used to treat **mood disorders** such as *haloperidol*, *thioridazine*, *perphenazine*).
- *Anti-arrhythmic agents* (drugs used to treat an **irregular heartbeat** such as *amiodarone*, *propafenone*, *quinidine* and *flecainide*).
- *Antifungals* (*terbinafine*).
- *Antihistamines* (drugs used to treat the symptoms of **allergic reactions**)

Taking this medicine regularly, particularly for a long time, can lead to addiction. Only use this medicine as described in the leaflet.

Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Speak to your doctor if you experience withdrawal symptoms.

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 experience the following, stop taking this medicine immediately and contact your doctor:

- A feverish generalised redness of the skin (erythema) associated with pustules (See section 4)
- Sudden severe headaches, nausea, vomiting, confusion, fits, visual disturbances.
- Sudden abdominal pain or rectal bleeding due to inflammation of the colon (ischemic colitis). (See section 4.)
- Sudden loss of vision. Reduction of blood flow to your optic nerve may occur with this medicine. (See section 4).

! If you are pregnant or breastfeeding

- If you are pregnant or breastfeeding, 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 drowsiness. If affected, do not operate machinery. **Avoid alcoholic drink.**
- This medicine can affect your ability to drive. Do not drive whilst taking this medicine until you know how this medicine affects you. It may be an offence to drive when taking this medicine if your ability to drive safely is affected.

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

There is further information for patients who are intending to drive in the UK - go to:
www.gov.uk/drug-driving-law

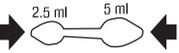
! Some of the ingredients can cause problems

- Each 5 ml of this medicine contains 2.8 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.
- This medicine contains 208 mg of alcohol (ethanol) in each 5 ml. The amount in 5 ml of this medicine is equivalent to less than 6 ml beer or 3 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.
- This medicine contains 5 mg sodium benzoate (E211) in each 5 ml.
- Methyl hydroxybenzoate (E218) may cause allergic reactions (possibly delayed).
- The red colouring, Ponceau 4R (E124) in this medicine may cause allergic reactions.
- This medicine contains 1 g sorbitol in each 5 ml. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.
- This medicine contains less than 1 mmol sodium (23 mg) per 5 ml, that is to say essentially 'sodium-free'.

3 How to take this medicine

Check the table that follows to see how much medicine to take.

- For oral use only.
- Always **shake the bottle** thoroughly before use.
- Do not take more medicine than the label tells you to.
- Do not use to sedate a child.
- Do not overfill the spoon.

There is a double-ended spoon in the pack. 

i Children under 12 years Do not give 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	Take two large 5 ml spoonfuls every 4 - 6 hours, up to 4 times a day
<ul style="list-style-type: none">■ Do not take more than 4 doses in 24 hours.■ Leave at least 4 hours between doses.■ If symptoms persist or worsen stop use and talk to your doctor or pharmacist.	

! If anyone has too much

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

If you take more of this medicine than you should, you may experience the following symptoms: nausea and vomiting, involuntary muscle contractions, agitation, confusion, somnolence, disturbances in consciousness, involuntary and rapid eye movements, cardiac disorders (rapid heart beating), coordination disorders, psychosis with visual hallucinations, and hyperexcitability. Also, other types of hallucinations, psychotic disorders, seizures, clumsiness, dizziness, speech problems, lack of energy, high blood pressure, tremor, or constricted or dilated pupils.

Other symptoms in case of massive overdose may be: coma, severe breathing problems, and convulsions.

Contact your doctor or hospital straight away if you experience any of the above symptoms.

! 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.

! Drug Withdrawal

When you stop taking this medicine, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

How do I know if I am addicted?

If you notice any of the following signs whilst taking this medicine, it could be a sign that you have become addicted.

- You need to take the medicine for longer than advised
- You feel you need to use more than the recommended dose

- You are using the medicine for reasons other than those indicated
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again.

If you notice any of these signs, it is important you talk to your doctor or pharmacist.

4 Possible side-effects

Like all medicines, Multi-Action Actifed Dry Coughs can cause side-effects, although not everybody gets them.

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

- Reduced blood flow to the heart which can cause angina (discomfort or pain in the chest, neck, back, jaw, shoulders or arms), or heart attack.
- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.
- Allergic reactions including skin rashes such as hives (which may be severe and include blistering or peeling of the skin) and itching.
- Feeling unusually tired, unexpected bruising or bleeding and getting more infections (such as colds) than normal.
- Hallucinations or paranoid delusions (seeing or hearing things that are not there, irrational thoughts or feelings).
- 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 onset of severe headache, nausea, vomiting, confusion, fits, visual disturbances.
- Inflammation of the colon due to insufficient blood supply (ischaemic colitis). Symptoms may include sudden abdominal pain or rectal bleeding.
- Sudden loss or reduction of vision which may be due to reduced blood flow to the optic nerve (ischaemic optic neuropathy).

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

- Trouble passing water (especially in men with prostate problems)

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, dizziness, drowsiness or nervousness

- Difficulty performing tasks
- Blurred vision
- Thickened mucus, dry mouth, upset stomach or nausea

Rare (may affect up to 1 in 1000 people)

- Depression or feeling confused
- Tremors, shakiness or slurred speech
- Low blood pressure
- Sleep disturbances
- An increased awareness of the heartbeat (palpitations)

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

- Anxiety, irritability or feeling jittery or feelings of extreme happiness
- Restlessness
- A fast or irregular heartbeat
- Tingling or numbness of the hands or feet (Pins and needles)
- High blood pressure
- Dependence and addiction (see section “How do I know if I am addicted?”)
- Dry throat or nose or nose bleeds
- Shallow breathing
- Stomach pain, diarrhoea or vomiting
- Pain when passing water
- Feeling tired

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side-effects you can help provide more information on the safety of this medicine.

5 Storing this medicine

Do not store this product above 25°C.

Keep the bottle in the outer carton and away from light.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Further Information

What's in this medicine?

The active ingredients in 5 ml of Multi-Action Actifed Dry Coughs are:

Triprolidine hydrochloride 1.25 mg, pseudoephedrine hydrochloride 30 mg and dextromethorphan hydrobromide 10 mg.

Other ingredients are: Sorbitol, sucrose, sodium benzoate (E211), methyl hydroxybenzoate (E218), Ponceau 4R (E124) (sodium), alcohol, blackberry flavour (ethanol), levomenthol, vanillin and purified water.

What the medicine looks like

Multi-Action Actifed Dry Coughs is a clear red liquid available in 100 ml bottles.

Marketing Authorisation Holder: McNeil Products Limited, 50-100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG.

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

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This leaflet was revised January 2022.

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