

LEAFLET TEXT

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Benlyn

MUCUS

COUGH PLUS

Decongestant syrup

Guaifenesin & Pseudoephedrine

- This medicine is used to relieve chesty coughs and help clear the stuffy, blocked up feeling in your nose and sinuses and reduce catarrh.
- This medicine is for use by adults and children aged 12 years and over.
- **Do not take this medicine:**
- There are some people who should not take 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**. These are shown in the table. 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 and what it is used for

Benlyn Mucus Cough plus Decongestant Syrup is a medicine which is used to relieve chesty coughs, help clear the stuffy, blocked up feeling in your nose and sinuses and reduce catarrh. The syrup contains pseudoephedrine hydrochloride, which is a decongestant that relieves nasal and sinus congestion and guaifenesin, which is an expectorant that helps to loosen the mucus in your throat and chest.

This medicine is for use by adults and children aged 12 years and over.

2 What you need to know 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

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doctor or pharmacist.

Do not take this medicine...

- If you have ever had a **bad reaction** to any of the ingredients of this medicine (listed in section 6).
 - If you have **high blood pressure** or **heart disease**.
- If you are taking *beta blockers* (used to treat **high blood pressure**).
- If you have **diabetes**.
- If you have an **overactive thyroid gland**.
- If you have **glaucoma** (increased pressure in the eye).
- If you have **phaeochromocytoma** (a rare tumour which affects your heart rate and blood pressure).
- If you have severe acute (sudden) or chronic (long-term) **kidney disease or kidney failure**
- 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 stimulants or appetite suppressants or drugs used to treat **congestion** and **asthma** (*Sympathomimetic drugs*).
- If you have had a **cough** for a few weeks, or a cough which brings up any blood or a lot of mucus that may be caused by **asthma** or **emphysema**.
- If you are taking **any other cough and cold medicine**.
- **For a child under 12 years old.**

If any of these apply to you, **get advice from a doctor or pharmacist without taking Benylin Mucus Cough plus Decongestant Syrup.**

Talk to your doctor or pharmacist...

- If you have **kidney or severe liver problems**.
- If you have **blocked arteries or veins** (occlusive vascular disease).
- If you have **alcohol dependence**.
- If you are being treated for a **thyroid disorder**.
- If you have difficulty passing water and / or an enlarged **prostate** (which may mean you need to pass water more often).
- If your **cough** keeps re-occurring or you have a **cough** with a **fever, rash** or **persistent headache**.
- If you are taking any **other medicines**, including:
 - *Antihypertensives* (drugs used to treat **high blood pressure** such as *guanethidine, methyl dopa, adrenergic neurone blockers debrisoquine, bretylium* and *betanidine*).
 - *Tricyclic antidepressants* (used to treat **mood disorders**).
 - *Moclobemide* (used to treat **mood disorders**).

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- *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**).
- *Anticholinergic drugs* (drugs used to treat **cramps** and **spasms** such as *atropine*).

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 erythema associated with pustules (see section 4).
- Sudden severe headaches, nausea, vomiting, confusion, fits, visual disturbances.
- Sudden abdominal pain or rectal bleeding may occur with this medicine, due to inflammation of the colon (ischaemic colitis). If you develop these gastro-intestinal symptoms, stop taking this medicine and contact your doctor or seek medical attention immediately (see section 4).
- Reduction of blood flow to your optic nerve may occur with this medicine. If you develop sudden loss of vision, stop taking this medicine and contact your doctor or seek medical attention immediately (see section 4).

If you are pregnant or 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.

Special warnings about this medicine

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 Mucus Cough plus Decongestant Syrup 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)

Some of the ingredients can cause problems

- Each 5 ml of this medicine contains 3 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 less than 1 mmol sodium (23 mg) per 5 ml, that is to say essentially 'sodium-free'.
- This medicine contains 0.02 mg benzyl alcohol in each 5 ml. Benzyl alcohol may cause allergic reactions. Ask your doctor or pharmacist for advice if you are

pregnant or breast-feeding, or

turn over

if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).

- This medicine contains 190 mg of alcohol (ethanol) in each 5 ml dose. The amount in a 5 ml dose of this medicine is equivalent to less than 5 ml beer or 2 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.
- Methyl hydroxybenzoate and propyl hydroxybenzoate may cause allergic reactions such as skin rash; this may happen after a few days.
- The colourings Ponceau 4R (E124) and Sunset Yellow (E110) in this medicine may cause allergic reactions.

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 overfill the spoon.

There is a double-ended spoon in the pack.

Children under 12 years

Do not give to children under 12 years.

Adults and children over 12 years

Age	Dose
Adults and children aged 12 years and over.	Two large 5 ml spoonfuls 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 get worse, stop use and talk to your doctor.

If anyone has too much

If anyone has taken too much contact a doctor or your nearest Accident and Emergency Department (Casualty) 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

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hours ago. **Do not** take a double dose.

4 Possible side-effects

Like all medicines, this medicine can cause side-effects, although not everybody gets them.

If you experience any of the following, stop using the 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.
- Stroke (weakness of the face, arms or legs, or speech problems).
- 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.
- 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 and peeling of the skin) and itching.
- Hallucinations or paranoid delusions (seeing or hearing things that are not there, irrational thoughts or feelings).
- Inflammation of the colon due to insufficient blood supply (ischaemic colitis). Symptoms may include sudden abdominal pain or rectal bleeding.

If you experience any of the following, stop using the 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, nervousness or dizziness
- Dry mouth or nausea

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)
- Anxiety, restlessness, irritability, feeling jittery or

feelings of extreme happiness

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- A fast or irregular heartbeat or an increased awareness of the heartbeat (palpitations)
- Sleep disturbances
- Stomach pain, diarrhoea or vomiting
- Pain when passing water
- High blood pressure
- Drowsiness
- Reduced blood flow to the optic nerve (Ischaemic optic neuropathy)
- Tingling or numbness of hands or feet (Pins and needles)
- A tremor or shakiness

Stop using Benylin Mucus Cough plus Decongestant Syrup 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

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 above 25°C.

Do not refrigerate.

Keep the product out of the sight and reach of children.

Keep the container in the outer carton.

Do not use this medicine after the expiry date which is stated on the carton after 'Exp'. 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 to protect the environment.

6 Further information

What's in this medicine?**The active ingredients in Benylin Mucus Cough plus**

Decongestant Syrup are: 100 mg Guaifenesin and 30 mg Pseudoephedrine hydrochloride in each 5 ml spoonful.

Other ingredients are: Sucrose, glycerol, methyl hydroxybenzoate (E218), propyl hydroxybenzoate (E216), ethanol (alcohol), Ponceau 4R (E124), flavouring (wild cherry (sodium, benzyl alcohol) and menthol), Sunset Yellow (E110) and purified water.

What the medicine looks like

Benylin Mucus Cough plus Decongestant Syrup is a clear

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orange-red cherry flavoured liquid available in 100 ml glass bottle.

Marketing Authorisation holder: McNeil Products Ltd, 50 - 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK.

Manufacturer: Delpharm Orléans, 5 avenue de Concy, 45071 Orléans, Cedex 2, France.

This leaflet was last revised in April 2024.

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