

Package leaflet: Information for the user

Benylin Phlegm Cough plus Decongestant Syrup

Guaifenesin 100mg/5ml

Pseudoephedrine Hydrochloride 30mg/5ml

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

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1. What Benylin Phlegm Cough plus Decongestant Syrup is and what it is used for

Benylin Phlegm Cough plus Decongestant 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 you use Benylin Phlegm Cough plus Decongestant Syrup

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.

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 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 **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.**
- For a child under 12 years old.

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

! Warnings and precautions

! Talk to your doctor or pharmacist...

- If you have **kidney or severe liver problems.**
- If you have **prostate problems** (difficulty with passing water or needing to pass water often).
- 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 your **cough lasts for more than 5 days** or keeps re-occurring or you have a **cough** with a **fever, rash or persistent headache.**
- If you have **epilepsy.**
- If you are being treated for a **thyroid disorder.**
- If you have **blocked arteries or veins** (occlusive vascular disease).

! Children

- Do not use to sedate a child.

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 Benylin Phlegm Cough plus Decongestant Syrup, due to inflammation of the colon (ischemic colitis). If you develop these gastro-intestinal symptoms, stop taking Benylin Phlegm Cough plus Decongestant 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 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 Benylin Phlegm Cough plus Decongestant Syrup. If you develop sudden loss of vision, stop taking Benylin Phlegm Cough plus Decongestant Syrup and contact your doctor or seek medical attention immediately. See section 4.

! Other medicines and Benylin Phlegm Cough plus Decongestant Syrup

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

- *Antihypertensives* (drugs used to treat **high blood pressure** such as *guanethidine*, *reserpine*, *methyldopa*, *adrenergic neurone blockers*, *debrisoquine*, *bretylum* and *betanidine*).
- *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).
- *Stimulants or appetite suppressants* and drugs used to treat **congestion** and **asthma** (*sympathomimetic drugs*).

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 machines

- This medicine may cause dizziness. If affected, do not drive or operate machinery.

! Anti-doping tests

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

! Benylin Phlegm Cough plus Decongestant Syrup contains Sucrose, methyl hydroxybenzoate (E218), propyl hydroxybenzoate (E216), sunset yellow (E110), Ponceau 4R (E124), ethanol, sodium and benzyl alcohol.

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- This medicine contains 188 mg of alcohol (ethanol) in each 5 ml dose. The amount of ethanol in of this medicine is equivalent to 5 ml beer or 2 ml wine. The amount of alcohol in this medicine is not likely to have an effect in adults and adolescents, and its effects in children are not likely to be noticeable. It may have some effects in younger children, for example feeling sleepy. The alcohol in this medicine may alter the effects of other medicines. Talk to your doctor or pharmacist if you are taking other medicines. If you are pregnant or breast-feeding, talk to your doctor or pharmacist before taking this medicine. If you are addicted to alcohol, talk to your doctor or pharmacist before taking this medicine.
- This medicine contains 3.0g sucrose per 5ml. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. This should be taken into account in patients with diabetes mellitus.
- 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.
- This medicine contains less than 1 mmol sodium (23 mg) per 5ml, that is to say essentially 'sodium-free'.
- This medicine contains 0.02mg benzyl alcohol in each 5 ml dose which is equivalent to 0.004 mg per ml. Benzyl alcohol may cause allergic reactions. This medicine must be used with caution in patients with renal or hepatic impairment, or in patients who are pregnant or breast-feeding, because of the risk of accumulation and toxicity (metabolic acidosis).

3. How to use Benylin Phlegm Cough plus Decongestant Syrup

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 use more than the stated dose shown in the table.
- Do not overfill the spoon.

There is a double-ended spoon in the pack. (pictogram of spoon).

Children under 12 years

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

Adults and children aged 12 years and over

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 worsen talk to your doctor or pharmacist	

! If you use more Benylin Phlegm Cough plus Decongestant Syrup 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 Benylin Phlegm Cough plus Decongestant 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, this medicine can cause side-effects, although not everybody gets them.

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

- Stop using Benylin Phlegm 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.
- 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 reactions 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 any of the following, stop using this medicine and talk to your doctor:

- A fast or irregular heartbeat or an increased awareness of the heartbeat (palpitations).
- Trouble passing water (especially men with prostate problems).
- Restlessness or sleep disturbances.
- 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 or dizziness.
- Dry mouth or nausea.

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, feeling jittery or feelings of extreme happiness.
- Tingling or numbness of the hands or feet (pins and needles).
- Stomach pain, diarrhoea or vomiting.
- Pain when passing water.
- High blood pressure.
- Inflammation of the colon due to insufficient blood supply (ischemic colitis).
- Tremors.
- 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 Benylin Phlegm Cough plus Decongestant Syrup

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 in order to protect from light.

Do not use after the expiry date stated on the 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 to protect the environment.

6. Contents of the pack and other information

What Benylin Phlegm Cough plus Decongestant Syrup contains

The active ingredients in Benylin Phlegm Cough Plus Decongestant 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), levomenthol, Ponceau 4R (E124), Sunset Yellow (E110), Wild cherry flavouring (containing ethanol, sodium and benzyl alcohol), and purified water.

What Benylin Phlegm Cough plus Decongestant Syrup looks like and the contents of the pack

Benylin Phlegm Cough Plus Decongestant is a clear orange-red cherry flavoured liquid available in 100 ml glass bottles.

Marketing Authorisation holder: Johnson & Johnson (Ireland) Limited, Airton Road, Tallaght, Dublin 24, Ireland.

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

This leaflet was revised in

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