



diphenhydramine, paracetamol, pseudoephedrine

- This medicine is used for the treatment of cold and flu symptoms, including aches, pains and fever (high temperature), cough and congestion.
- This medicine is for use by adults and children aged 6 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.** Children and adults need different amounts. See *section 3* ▶

I What the medicine is for

Benylin 4 Flu Tablets are used to help relieve cold and flu symptoms. The tablets contain paracetamol which helps to relieve aches and pains and fever (high temperature), diphenhydramine, which is an antihistamine that helps relieve coughing, sneezing and runny nose and pseudoephedrine, which is a decongestant that helps unblock stuffy noses. The medicine is for use in adults and children aged 6 years and over.

2 Before using 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.

X Do not use this medicine...

- If you are taking any other medicines containing **paracetamol**.
- If you have ever had a **bad reaction** to any of the ingredients.
- If you have **heart disease** or **high blood pressure**.
- If you have **diabetes**.
- If you have an **overactive thyroid**.
- If you have **phaeochromocytoma** (rare tumour which affects your heart rate and 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 **suffer from or have had closed angle glaucoma** (increased pressure in the eye).
- If you are taking **beta blockers** (used to treat high blood pressure).
- For a child under **6 years of age**.
- If you are taking **any other cough and cold medicine**.
- If you have **severe kidney problems**.

If any of these apply to you now or in the past, **get advice from a doctor or pharmacist without using Benylin 4 Flu Tablets**.

! Talk to your doctor or pharmacist...

- If you have **kidney** or **liver problems**, including alcoholic liver disease.
- If you have **difficulty passing water** (urinary retention).
- If you have **blocked arteries or veins** (occlusive vascular disease).
- If you have a **persistent cough** such as occurs with **asthma**, have **asthma**, are suffering from an **asthma attack** or a **cough that produces a lot of mucus (phlegm)**.
- If you are taking any **other medicines** including:
 - **Antimuscarinic** drugs e.g.:
 - **tricyclic antidepressants** (drugs to treat **mood disorders**).
 - **atropine** (used to treat some **eye conditions** and occasionally **bowel conditions**).
 - **CNS depressants** e.g.:
 - **hypnotics (sleeping tablets)** including barbiturates).
 - **minor tranquilisers** (drugs used to **relax muscles** or **decrease anxiety**).
 - **opioid analgesics** (drugs used to **relieve pain** e.g. codeine, tramadol, morphine).

- **antipsychotics** (drugs used to treat **mood disorders**).
- **Antihypertensives** (drugs used to treat **high blood pressure** including alpha and beta blockers).
- **sympathomimetic drugs** (stimulants or appetite suppressants and drugs used to treat **congestion** and **asthma**).
- **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).
- **oral contraceptives** ("the pill").
- **metoclopramide** or **domperidone** (used to treat **nausea and vomiting**).
- **colestyramine** (used to treat **high cholesterol**).
- **anticoagulants** (drugs that **thin the blood**, such as warfarin).
- **anticonvulsants** (drugs to treat **epilepsy**).

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

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

! If you are pregnant or breast-feeding

- Ask your doctor or pharmacist for advice before taking this medicine if you might be pregnant or are breast-feeding.

! Special warnings about this medicine

- You can use this medicine while you are taking oral contraceptives ("the pill") or anticonvulsants (drugs used to treat epilepsy), but the medicine may not work so well on your pain or fever.
- This medicine may cause drowsiness. If affected, do not drive or operate machinery. Avoid alcoholic drink.
- This product may cause drowsiness. It should **NOT** be used to sedate a child.

! Some of the ingredients can cause problems

- This medicine contains Sunset yellow (E110). This may cause allergic reactions.
- This medicine contains 1.2 mg sodium per tablet. To be taken into consideration by patients on a controlled sodium diet.

turn over ▶

spot = 12 x 2 centered in the margin of 14 mm

Distance between cutted line/middel of the spot = 83.6 mm



3 How to take this medicine

Check the tables below to see how much medicine to take.

- For oral use only.
- Do not take more than the stated dose shown below.

i Children under 6 years

This medicine is not recommended for children under 6 years old.

i Adults and children aged 6 years and over

| Age | Dose |
|--|---|
| Adults and children aged 12 years and over | Take two tablets , up to 4 times a day |
| Children 6 – 12 years | Take one tablet , up to 4 times a day |

- Leave at least 4 hours between doses.
- Do not take more than 4 times a day.
- If symptoms persist or worsen, talk to your doctor or pharmacist.
- Do not give to a child under 12 years of age for more than 5 days without consulting your doctor.

⚠ If anyone has too much

Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.

⚠ If you forget to take the medicine

You should only take this medicine as required following the dosage instructions above carefully. 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

Benylin 4 Flu Tablets can have side-effects, like all medicines, although these don't affect everyone and are usually mild.

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

- Allergic reactions including skin rashes (which may be severe and include blistering and peeling of the skin) and itching.

- Allergic reactions to other medicines containing *sympathomimetic drugs* (stimulants or appetite suppressants) and drugs used to treat congestion and asthma).
- Becoming unusually tired, unexpected bruising or bleeding and getting more infections (such as colds) than usual. These are very rare effects in people taking paracetamol.
- Hallucinations and paranoid delusions.
- Rarely people can experience fits.
- Rarely abnormal blood test results for liver function.

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

- Rarely people can have an increased heartbeat, an increased awareness of the heartbeat (palpitations) and high blood pressure.
- Restlessness and sleep disturbances.

Other effects that may occur include:

- Irritability, anxiety, excitability, nausea and sickness.
- Commonly: drowsiness, including some difficulty performing tasks, headache, upset stomach, difficulty in passing urine, stimulation, blurred vision, dry mouth, thickened mucus.
- Rarely: low blood pressure, tremor, shakiness, slurred speech, dizziness, confusion, depression, blood disorders.

If you experience any side-effects not included in this leaflet, or are not sure about anything, **talk to your doctor or pharmacist.**

5 Storing this medicine

Do not store this product above 25°C.

Store in the original packaging.

Keep the container in the outer carton.

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

Do not use your medicine after the date shown as an expiry date on the packaging.

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 4 Flu Tablets are: 500 mg Paracetamol, 22.5 mg Pseudoephedrine hydrochloride, 12.5 mg Diphenhydramine hydrochloride.

Other ingredients are: Microcrystalline cellulose, pregelatinised maize starch, povidone, crospovidone, macrogol 6000, croscarmellose sodium, stearic acid, magnesium stearate, hypromellose, titanium dioxide (E171), quinoline yellow (E104), sunset yellow (E110) and talc.

What the medicine looks like

Benylin 4 Flu Tablets are orange film coated tablets, available in packs of 24.

Marketing Authorisation holder:

McNeil Products Ltd, Maidenhead, Berkshire, SL6 3UG, UK.

Manufacturer: Janssen Cilag, Domaine de Maigremont, 27100 Val de Reuil, France.

This leaflet was revised November 2011.

Benylin is a registered trade mark.

7 Information about treating cough and cold in children

It's normal for children to get 8 or more colds in a year. Because colds are caused by viruses, not bacteria, antibiotics don't help. Here are simple steps to help your child who has a cough or cold.

- **If they are hot/feverish:** Increase the amount of fluid your child normally drinks. Lower their temperature with a paracetamol or ibuprofen medicine which has doses for children.
- **For coughs:** Coughing serves a purpose, it helps clear phlegm and mucus. Give the child plenty of warm clear fluids to drink.
- **To help with breathing:** Plain saline nose drops / sprays can help with blocked noses.

McNeil
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