



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 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.

  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.

#### I What the medicine is for

Benylin 4 Flu Liquid is a medicine which is used to help relieve cold and flu symptoms. The liquid contains paracetamol, an analgesic which helps to relieve aches and pains and fever (high temperature), diphenhydramine, an antihistamine which helps dry secretions and relieve coughing and pseudoephedrine, a decongestant which helps unblock stuffy noses.

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.

### X Do not use this medicine...

- If you are taking any other medicines containing paracetamol or sympathomimetic drugs (stimulants or appetite suppressants and drugs used to treat congestion and asthma) including those that are not taken orally.
- 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 a 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).
- 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 Liquid.

### ⚠ Talk to your doctor or pharmacist...

- If you want to give this medicine to a child under 12 years old.
- If you have liver or kidney problems.
- If you have **difficulty passing water** (urinary retention).
- If you have **prostate disease**.
- 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 tranquillisers (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).
- 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.

#### Alf 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.



## ASpecial warnings about this medicine

- You can use this medicine while you are taking oral contraceptives ("the pill") or anticonvulsant tablets 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

# Some of the ingredients can cause problems

- Ponceau 4R (E124) may cause allergic type reactions
- This medicine contains 10 vol % of ethanol (alcohol) i.e. up to 400 mg per 20 ml, which is the same as 40 ml of beer or 17 ml of wine per 20 ml. This can be harmful for those suffering from alcoholism. The ethanol content should be taken into account for pregnant or breast-feeding women, children or high risk groups such as patients with liver disease or epilepsy.
- This medicine contains sodium (26 mg per 20 ml). This should be taken into account by patients on a controlled sodium diet.

# 3 How to take this medicine

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

- For oral use only.
- Do not take more than the stated dose shown below.
- A measuring cup is included in the pack.

### Children under 12 years

Not recommended for children under 12 years old.

### Adults and children aged 12 years or over

Age	Dose
Adults and children aged 12 years or over	Take 20 ml (fill measuring cup to 20 ml mark) up to 4 times a day if necessary

- Leave at least 4 hours between doses.
- Do not take more than 4 times a day.
- If symptoms persist, talk to your doctor or pharmacist.

### Alf 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.

### Alf 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.

#### **4** Possible side-effects

Benylin 4 Flu Liquid 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.
- People can experience fits.
- 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 (feeling sick or queasy) and vomiting (being sick).
- Drowsiness, difficulty performing tasks, insomnia.
- Headache, upset stomach, difficulty in passing urine, stimulation, blurred vision, dry mouth, thickened mucus.

 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  $30^{\circ}$ C. Keep the container in the outer carton. Keep the container tightly closed.

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 20 ml of Benylin 4 Flu liquid are: Paracetamol 1000 mg, Pseudoephedrine hydrochloride 45 mg, Diphenhydramine hydrochloride 25 mg.

Other ingredients are: Polyethylene glycol, glycerol, propylene glycol, saccharin sodium, citric acid monohydrate, sodium benzoate, eucalyptol, menthol, sodium carboxymethylcellulose, sodium citrate, ethanol, quinoline yellow (E104), Ponceau 4R (E124), Patent Blue V (E131), flavourings (honey, lemon, cream) and water.

#### What the medicine looks like

Benylin 4 Flu liquid is a clear orange to brown oral solution, available in 200 ml glass bottles.

#### **Marketing Authorisation holder:**

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

**Manufacturer:** McNeil Manufacturing, 5 avenue de Concyr, 45071 Orleans, Cedex 2, France.

This leaflet was revised August 2009.

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