

## PATIENT INFORMATION LEAFLET

### Benlyn Four Flu® Film-Coated Tablets

(paracetamol 500mg / diphenhydramine hydrochloride 12.5mg / pseudoephedrine hydrochloride 22.5mg)

Your medicine is available using the above name but will be referred to as Benlyn Four Flu throughout the leaflet.

### Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However you still need to take Benlyn Four Flu carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects get serious or if you notice any side effects not listed in this leaflet, please consult your doctor or pharmacist.

### In this leaflet

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### 1. What Benlyn Four Flu is and what it is used for

Benlyn Four Flu is 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 10 years and over.

### 2. Before taking Benlyn Four Flu

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.

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

- If you are taking any other medicines containing **paracetamol**.
- If you have ever had an **allergic (hypersensitivity) 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 **10 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 Benlyn Four Flu**.

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

- If you have **liver** or **kidney problems**.
- If you have **difficulty passing water** (urinary retention).
- If you have an **enlarged prostate**.
- 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)**.

#### Taking other medicines

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).
- *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**.

#### Pregnancy and breast feeding

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

#### Take special care with Benlyn Four Flu

- 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.
- There is a greater risk of overdose in patients with alcoholic liver disease.

#### Driving and using machines

- 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.

#### Important information about some of the ingredients of Benlyn Four Flu

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

### 3. How to take Benlyn Four Flu

#### Check the tables overleaf to see how much medicine to take.

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

#### Children under 10 years

This medicine is not recommended for children under 10 years old.

## Adults and children aged 10 years and over

Age	Dose
Adults and children aged 16 years and over	Take <b>two tablets</b> , up to 4 times a day
Children 10 – 15 years	Take <b>one tablet</b> , 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 16 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 Four Flu 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.
- An abnormal decrease in the number of platelets in the blood.
- High fever and/or a sharp drop in level of white blood cells.

### 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 vomiting.
- 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 and depression.

### 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, Earlsfort Terrace, IRL - Dublin 2  
Tel: +353 1 6764971 Fax: +353 1 6762517  
Website: [www.hpra.ie](http://www.hpra.ie) E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

By reporting side effects, you can help provide more information on the safety of this medicine.

## 5. How to store Benylin Four Flu

Keep this medicine out of the sight and reach of children. Do not store above 25°C.

Store in the original package. Keep container in the outer carton.

Do not use this medicine after the expiry date (Exp) which is marked on the blisters and outer carton. This 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 any medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

### What's in this medicine?

Each tablet contains the active ingredients: 12.5mg diphenhydramine hydrochloride, 500mg paracetamol, and 22.5mg pseudoephedrine hydrochloride.

The tablets also contain: 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 Four Flu are orange, biconvex, film coated tablets with no markings.

Benylin Four Flu is available in blister packs containing 24 tablets.

### Manufacturer

Manufactured by: Janssen Cilag S.A.,  
Domaine de Maigremont, 27100 Val de Reuil, France.

Procured from within the EU and repackaged by:  
Doncaster Pharmaceuticals Group Ltd., Kirk Sandall,  
Doncaster, DN3 1QR, UK.

PPA holder: Imbat Ltd., Unit L2, North Ring Business Park,  
Santry, Dublin 9.

Distributed by: Eurodrug Ltd., Unit L2, North Ring Business  
Park, Santry, Dublin 9.

PPA No: 1151/130/1

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Benylin® is a registered trademark of Johnson & Johnson

## 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.

Blind or partially sighted?  
Is this leaflet hard to see or read?

Call +44 (0) 1302 365000  
(Regulatory)

Please be ready to give the following information:  
Product name: Benylin Four Flu Film-Coated Tablets  
Reference No: 1151/130/1