

Package leaflet: Information for the patient



Paracetamol 500 mg, Diphenhydramine hydrochloride 12.5 mg, Pseudoephedrine hydrochloride 22.5 mg

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 Benylin 4 Flu tablets 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 stop use 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.

What is in this leaflet

1. What Benylin 4 Flu tablets are and what they are used for
2. Before taking Benylin 4 Flu tablets
3. How to take this medicine
4. Possible side effects
5. How to store Benylin 4 Flu tablets
6. Further information
7. Information about treating cough and cold in children

1. What Benylin 4 Flu tablets are and what they are used 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 10 years and over.

2. Before taking Benylin 4 Flu tablets

This medicine is suitable for most people, but a few should not use it. If you are in any doubt, talk to your doctor or pharmacist.

X Do not take this medicine...

- If you are taking any other **cough and cold medicines** or medicines containing **paracetamol**.
- If you have ever had a **bad reaction** to paracetamol, pseudoephedrine or diphenhydramine or any of the other ingredients in this medicine (listed in section 6).
- If you have **heart disease** or **high blood pressure**.
- If you have **diabetes**.
- If you have an **overactive thyroid gland**.
- If you have **Pheochromocytoma** (rare tumor 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 are taking **stimulants** or **appetite suppressants** and drugs used to treat **congestion** and **asthma** (*sympathomimetic drugs*).
- If you are using any other medicines containing **diphenhydramine**, including those used on large areas of the skin.
- If you have **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 have **severe acute (sudden) or chronic (long-term) 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 **severe liver problems**.
- If you have **alcohol dependence**.
- If you have difficulty with passing water and / or an enlarged prostate (which may mean you need to pass water more often).
- If you are **susceptible to glaucoma** (increased pressure in the eye).
- If you have **blocked arteries or veins** (occlusive vascular disease).

- If you have **bronchitis, emphysema** or **asthma**, or have had a **cough for a few weeks, or a cough with a lot of mucus (phlegm)**.
- If you are being treated for a **thyroid disorder**.

! Taking other medicines

If you are taking any **other medicines** including:

- **Tricyclic antidepressants** (drugs to treat **mood disorders**).
- **Anticholinergic drugs** (drugs used to treat **cramps and spasms** such as *atropine*).
- **Hypnotics (sleeping tablets)** including *barbiturates*.
- **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** such as *guanethidine, methyldopa, adrenergic neurone blockers, debrisoquine, bretylium* and *betanidine*).
- **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** (drug used to help **contractions** during **childbirth**).
- **Oral contraceptives** ("the pill").
- **Metoclopramide** or *domperidone* (used to treat **nausea and vomiting**).
- **Cholestyramine** (used to **lower blood cholesterol**).
- **Anticoagulants** (drugs used to **thin the blood**, such as *warfarin*).
- **Anticonvulsants** (drugs to treat **epilepsy**).
- **Flucloxacillin** (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

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**.

Please inform your doctor or pharmacist if you are taking flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which

may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.

! 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 abdominal pain or rectal bleeding may occur with this medicine, due to inflammation of the colon (ischemic colitis). See section 4.
- Sudden severe headaches, nausea, vomiting, confusion, fits, visual disturbances.
- 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.

During treatment with Benylin Four Flu Tablets, tell your doctor straight away if:

- If you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

! 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.

! Take special care with Benylin 4 Flu tablets

- 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 product may cause drowsiness. It should NOT be used to sedate a child.

- 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 Four Flu 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).'

! Driving and using machines

- This medicine may make you feel sleepy. If this happens do not drive or use tools or machines. Do not drink alcohol.

! Important information about some of the ingredients of Benylin 4 Flu tablets

- This medicine contains Sunset yellow (E110). This may cause allergic reactions.
- This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.
- One of the active ingredients in Benylin 4 Flu Tablets, pseudoephedrine, has the potential to be abused and large doses of pseudoephedrine can be toxic. Continuous use may lead to taking more Benylin 4 flu Tablets than the recommended dose to get the desired effect, resulting in an increased risk of overdosing. The recommended maximum dose and treatment duration should not be exceeded (see section 3).

3. How to take this medicine

Check the table that follows to see how much medicine to take.

- For oral use only.
 - Do not take more than the stated dose shown below.
- 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 two tablets, up to 4 times a day
Children 10 – 15 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, stop use and 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

Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause 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

Like all medicines, Benylin 4 Flu Tablets can have side-effects, although these don't affect everyone.

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

- Serious conditions affecting blood vessels in the brain known as posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS).
- 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.
- Allergic reactions including skin rashes such as hives

(which may be severe and include blistering and peeling of the skin) and itching.

■ Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.

■ Feeling unusually tired, unexpected bruising or bleeding and getting more infections (such as colds) than normal.

■ 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.

■ Sudden loss or reduction of vision which may be due to reduced blood flow to the optic nerve (Ischaemic optic neuropathy).

Stop using Benylin Four Flu Tablets 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

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

■ Trouble passing water (especially in men with prostate problems).

Other effects that may occur include:

Very Common (may affect more than 1 in 10 people)

■ Headache or drowsiness

Common (may affect up to 1 in 10 people)

■ Difficulty sleeping, nervousness or dizziness

■ Difficulty performing tasks

■ Dry mouth, thickened mucus or nausea

■ Blurred vision

■ Unusual weakness

Uncommon (may affect up to 1 in 100 people)

■ Irritability or confusion

■ Tinnitus (a persistent noise in the ears)

Rare (may affect up to 1 in 1000 people)

■ Depression

■ Tremor, shakiness or slurred speech

■ Low blood pressure

■ A fast or irregular heartbeat or an increased awareness of the heartbeat (palpitations)

■ Sleep disturbances

Not known (frequency cannot be estimated from the available data)

■ Anxiety, restlessness, feeling jittery or feelings of extreme happiness

■ Tingling or numbness of the hands or feet (pins and needles)

■ High blood pressure

■ Dry nose

■ Vomiting

■ Chest tightness or discomfort

■ Pain when passing water

■ Very rare cases of serious skin reactions have been reported with paracetamol.

■ A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2)

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

You can also report side effects directly in Malta via ADR Reporting at: www.medicinesauthority.gov.mt/adrportal.

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

5. How to store Benylin 4 Flu tablets

Do not store this product above 25°C.

Store in the original packaging.

Keep this medicine out of the sight and reach of children.

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.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help 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), quinoline yellow lake, 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:

JNTL Consumer Health I (Ireland) Ltd.

Block 5, High Street, Tallaght, Dublin 24, Ireland

Manufacturer: JNTL Consumer Health (France) SAS, Domaine de Maigremont, 27100 Val de Reuil, France.

This leaflet was last revised in

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.