



## Day & Night Tablets

day tablet: paracetamol 500 mg, pseudoephedrine hydrochloride 60 mg  
night tablet: paracetamol 500 mg, diphenhydramine hydrochloride 25 mg

- This medicine is used to relieve the symptoms of cold and flu.
- This medicine is for use by adults and children aged 12 years and over.
- This pack contains 2 different coloured tablets, for use at different times of the day. Read the leaflet carefully to ensure that you take the correct tablet at the appropriate time of day.
  - The white tablets contain paracetamol and pseudoephedrine and are for daytime use.
  - The blue tablets contain paracetamol and diphenhydramine and are for night time use only.
- **Follow the dosage instructions carefully.** There are different tablets for day and night time doses. See section 3 ►
- **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 ►

**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 Day and Night Tablets are used for the relief of cold and flu symptoms.

The white day time tablets contain paracetamol, an analgesic and antipyretic which helps to relieve pain and fever and pseudoephedrine hydrochloride, a decongestant which unblocks stuffy noses.

The blue night time tablets contain paracetamol and diphenhydramine hydrochloride, an antihistamine which helps clear catarrh and so aids sleep.

This medicine is for use in adults and children aged over 12 years.

## 2 Before taking this medicine

This medicine is suitable for most adults and children aged over 12 years 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 **very high blood pressure** or **severe heart disease**.
- If you have ever had a **bad reaction** to paracetamol or any of the other ingredients.
- If you are taking any other medicines containing **paracetamol** or a **decongestant**.
- If you are taking, or have taken in the last two weeks, **drugs for depression** known as Monoamine Oxidase Inhibitors (MAOIs).
- If you are **pregnant** or **breast-feeding**.

If any of these apply to you, **get advice from a doctor or pharmacist without using Benylin Day and Night Tablets.**

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

- If you have **liver** or **kidney problems**.
- If you have **heart disease** or **mild to moderate high blood pressure**.
- If you have **diabetes**.
- If you have an **overactive thyroid gland**.
- If you have **glaucoma** (increased pressure in the eye).
- If you have **prostate problems** (difficulty with passing water or needing to pass water often).

- If you are taking **alcohol**.
  - If you are taking any **other medicines**, including:
    - **anticholinergic** drugs e.g.:
      - **tricyclic antidepressants** (drugs used to treat **mood disorders**).
      - **barbiturates** (a kind of **sleeping tablet**).
      - **antidepressants** (drugs used to treat **mood disorders**).
      - **sympathomimetic drugs** (*stimulants or appetite suppressants*) and drugs used to treat **congestion** and **asthma**).
      - **antihypertensives** eg: methyldopa (drugs used to treat **high blood pressure**).
      - **colestyramine** (used to **lower blood cholesterol**).
      - **metoclopramide** or **domperidone** (used to treat **nausea and vomiting**).
      - **anticoagulants** (drugs used to **thin the blood**, such as warfarin).
      - **anticonvulsants** (drugs used to treat **epilepsy**).
      - **oral contraceptives** ("the pill").
      - **anticholinergics** eg: atropine
- 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 now or in the past, **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 are pregnant or breast-feeding.

### ! Special 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.
- Night time tablets may cause drowsiness. If affected, do not drive or operate machinery. Avoid alcoholic drink.

turn over ►

### 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.
- Take with a glass of water.

#### **i** Children under 12 years old

This medicine is not recommended for children under 12 years old.

#### **i** Adults and children aged 12 years and over

Age	Dose
Adults and children aged 12 years and over	<b>Day time</b> 1 white tablet every 4 - 6 hours, up to 3 times a day (one tablet in the morning, at mid-day and in the afternoon). <b>Night time</b> 1 blue tablet to be taken at night.

- Do not take more than 3 white tablets a day.
- Take only 1 tablet at a time and only at the times of day described in this table.
- Do not take the night time tablets during the day.
- If symptoms persist, talk to your doctor.
- Contains paracetamol. Do not exceed stated dose.

#### **!** 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 Day and Night 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 or peeling of the skin) and itching.

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

- A few people have had hallucinations but this is rare.
- Breathing difficulties.
- Swelling of the face, lips and/or tongue.
- A few men, especially men with prostate problems, may have trouble passing water.

#### Other effects which may occur include:

- Having trouble getting to sleep.
- Drowsiness, dizziness, blurred vision.
- Dry mouth, nose and throat.
- Upset stomach.

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 above 25°C.

Store in the original package.

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

Do not use after the end of the month 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 Day and Night tablets are:** Day Tablets: 500 mg Paracetamol and 60 mg Pseudoephedrine hydrochloride.  
Night Tablets: 500 mg Paracetamol and 25 mg Diphenhydramine hydrochloride.

#### Other ingredients are:

Day Tablets: Pregelatinised maize starch, povidone, crospovidone, stearic acid, microcrystalline cellulose, croscarmellose sodium and magnesium stearate.

Night Tablets: Microcrystalline cellulose, maize starch, sodium starch glycolate, pregelatinised maize starch, hydroxypropylcellulose, croscarmellose sodium, stearic acid, magnesium stearate and are coated with methylcellulose (methocel E5), Opaspray M-1F-4315B containing indigo carmine (E132), titanium dioxide (E171) and propylene glycol.

#### What the medicine looks like

Benylin Day & Night Tablets come in a carton containing 12 white oblong day-time tablets and 4 blue round night-time tablets.

#### Marketing Authorisation holder:

McNeil Healthcare (Ireland) Limited, Airton Road, Tallaght, Dublin 24, Ireland.

**Manufacturer:** Janssen-Cilag, Domaine de Maigremont, F27100 Val de Reuil, France

**This leaflet was revised August 2010.**

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Healthcare (Ireland) Ltd.