



DAY & NIGHT TABLETS

Paracetamol, Diphenhydramine, Pseudoephedrine

- 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.

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 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 take this medicine...

- If you have **high blood pressure** or **heart disease**.
- If you have **diabetes**.
- If you have a **phaeochromocytoma** (a rare tumour that affects your heart rate and blood pressure).
- If you have an **overactive thyroid gland**.
- If you have **glaucoma** (increased pressure in the eye).
- If you have **severe acute (sudden) or chronic (long-term) kidney disease or kidney failure**.
- 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 are taking **beta blockers** (used to treat **high 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** or drugs used to treat **congestion** and **asthma** (*sympathomimetic drugs*).
- If you are taking any other **cough and cold medicines** or medicines containing **paracetamol**.
- If you are using any other medicines containing **diphenhydramine**, including those used on large areas of the skin.

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 **kidney** or **severe liver problems**.
- If you have **alcohol dependence**.
- If you are **susceptible to glaucoma** (increased pressure in the eye).
- If you have **blocked arteries** or **veins** (occlusive vascular disease).
- If you are being treated for a **thyroid disorder**.
- If you have **difficulty with passing water** and/or an **enlarged prostate** (which may mean you need to pass water more often).
- 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 taking any **other medicines**, including:
 - **anticholinergic drugs** (drugs used to treat **cramps** and **spasms** such as *atropine*).
 - **tricyclic antidepressants** (used to treat **mood disorders**).
 - **hypnotics** (**sleeping tablets** including *barbiturates*).
 - **tranquillisers** (drugs used to **relax muscles** or **decrease anxiety**).

turn over ▶

- *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, methyl dopa, adrenergic neurone blockers, debrisoquine, bretteium 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**).
- *cholestyramine* (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**").
- *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 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 to you now or in the past, **talk to a doctor or pharmacist**.

⚠ If you experience the following, stop taking this medicine immediately and contact your doctor:

- A feverish generalised redness of the skin (erythema) associated with pustules. See section 4.
- Sudden severe headaches, nausea, vomiting, confusion, fits, visual disturbances.
- Sudden abdominal pain or rectal bleeding due to inflammation of the colon (ischemic colitis). See section 4.
- Sudden loss of vision. Reduction of blood flow to your optic nerve may occur with this medicine. See section 4.

⚠ If you are pregnant or 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.

⚠ 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.**
- This product may cause drowsiness. It should **NOT** be used to sedate a child. Cases of posterior reversible encephalopathysyndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) havebeen reported following use of medicines containing pseudoephedrine. PRES andRCVS are rare conditions that can involve reduced blood supply to the brain. Stop usingBenlylin Day and Night immediately and seek immediate medical assistance if youdevelop symptoms that may be signs of PRES or RCVS (see section 4 "Possible sideeffects" for symptoms).

⚠ Some of the ingredients can cause problems

- This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.
- One of the active ingredients in Benlylin Day and Night tablets, pseudoephedrine, has the potential to be abused and large doses of pseudoephedrine can be toxic. Continuous use may lead to taking more Benlylin Day and Night tables 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 medicine than the label tells you to.
- Take with a glass of water.

i Children under 12 years old

Do not give to children under 12 years old.

i Adults and children aged 12 years and over

Age	Dose
Adults and children aged 12 years and over	Day time 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). Night time 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 the table.
- Do not take the night time tablets during the day.
- If symptoms persist or worsen, stop use and talk to 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

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 Day and Night Tablets can have side-effects, although not everybody gets them.

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

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

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

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 which 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
- An increased awareness of the heartbeat (palpitations)
- Sleep disturbances

Other effects which may occur but it is unknown how often

- Serious conditions affecting bloodvessels in the brain known as posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS).
- Anxiety, restlessness or feelings of extreme happiness
- Tingling or numbness of the hands or feet (pins and needles)
- A fast or irregular heartbeat
- 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.

Stop using Benylin Day & Night 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



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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side-effects, you can help provide more information on the safety of this medicine.

5 Storing this medicine

Do not store 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 'Expiry'. The expiry date refers to the last day of that month.

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 hypromellose, indigo carmine (E132), titanium dioxide (E171) and propylene glycol.

What the medicine looks like

Benylin Day and Night Tablets are 12 white oblong day-time tablets and 4 blue round night-time tablets, available in packs of 16 tablets.

Marketing Authorisation holder: McNeil Products Ltd, High Wycombe, Buckinghamshire, HP12 4EG, UK.

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

This leaflet was revised May 2024.

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