

Package leaflet: Information for the user

Benylin Day & Night Tablets

Day Tablet: Paracetamol 500mg,
pseudoephedrine hydrochloride 60mg

Night tablet: Paracetamol 500mg,
diphenhydramine hydrochloride 25mg

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

What is in this leaflet

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1. What Benylin Day & Night Tablets are and what they are used for

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

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 (to relieve pain) and pseudoephedrine (a decongestant which unblocks stuffy noses) and are for daytime use.

The blue tablets contain paracetamol and diphenhydramine (an antihistamine which helps clear catarrh and so aids sleep) and are for night time use only.

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

2. What you need to know before you take Benylin Day & Night Tablets

Do not take Benylin Day & Night Tablets:

- If you are allergic to paracetamol, pseudoephedrine, diphenhydramine or any of the other ingredients of this medicine (listed in section 6)
- If you have diabetes

- If you have a phaeochromocytoma (a tumour which affects your heart rate and blood pressure)
- If you have high blood pressure or heart disease
- If you have an overactive thyroid
- If you have glaucoma (increased pressure in the eye)
- If you have severe kidney problems
- If you have lung disease or breathing difficulties
- If you are taking, or have taken, in the past 2 weeks drugs for depression known as Monoamine Oxidase Inhibitors (MAOIs)

If any of these apply to you, get advice from a doctor or pharmacist before using Benylin Day & Night Tablets.

Talk to your doctor or pharmacist before taking Benylin Day & Night Tablets

- if you are taking any other medicines containing paracetamol
- if you have liver or kidney problems
- if you have prostate problems (difficulty with passing water or needing to pass water often)
- if you have epilepsy
- if you have blocked arteries or veins (occlusive vascular disease)
- If you have the type of anaemia where your red blood cells get broken down (haemolytic anaemia) or any risk factors for this condition
- If you are being treated for a thyroid disorder
- If you have alcohol dependence
- If you weigh less than 50kg, suffer from chronic malnutrition or are dehydrated
- If you develop a feverish generalised erythema associated with pustules, stop taking this medicine and contact your doctor or seek medical attention immediately. See section 4.

Other medicines and Benylin Day & Night Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do NOT take these tablets with any other paracetamol, diphenhydramine or decongestant products.

Do NOT take these tablets with any other cough and cold products.

Special care is required as some of the following medicines may interact with these tablets:

- Tricyclic antidepressants (drugs used to treat mood disorders)
- Mocllobemide (used to treat **mood disorders**)
- Oxytocin (drug used to help **contractions** during childbirth)
- Cardiac glycosides (drugs used to control heart rhythms or contractions e.g. digoxin)
- Ergot alkaloids (used to treat migraine such as ergotamine and methysergide)

- Sympathomimetic drugs (stimulants or appetite suppressants and drugs used to treat congestion and asthma)
- Antihypertensives (drugs used to treat high blood pressure such as *guanethidine*, *methyldopa*, *adrenergic neurone blockers* *debrisoquine*, *bretylum*, *reserpine* and *betanidine*)
- Colestryamine (used to lower blood cholesterol)
- Metoclopramide or domperidone (used to treat nausea and vomiting)
- Anticoagulants (drugs used to thin the blood, such as warfarin)
- Anticholinergic drugs e.g. atropine
- Anticonvulsants (drugs used to treat epilepsy)
- Oral contraceptives ("the pill")

You may 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 and fever.

Benylin Day & Night Tablets with food, drink and alcohol

- Avoid alcoholic drink. Alcohol can increase the liver damage of a paracetamol overdose.

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.

Driving and using machines

Night time tablets may cause drowsiness. Day time tablets may cause dizziness. If affected, do not drive or operate machinery.

Anti-doping tests

This medicine contains pseudoephedrine hydrochloride, which may produce positive results in anti-doping tests.

3. How to take Benylin Day & Night Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Check the table below to see how much medicine to take

- For oral use only
- Do not take more than the stated dose below
- Take with a glass of water
- Always take this medicine exactly as in the table below.

Follow the dosage instructions carefully. There are different tablets for day and night time doses.

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 this table.
- Do not take the night time tablets during the day.
- If symptoms persist, talk to your doctor.
- Contain paracetamol. Do not exceed stated dose.

Use in children and adolescents

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

If you take more Benylin Day & Night Tablets than you should

Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of irreversible liver damage.

If you forget to take Benylin Day & Night Tablets

You should only take this medicine as required following the dosage instructions in the table 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 to make up for a forgotten tablet.

If you stop taking Benylin Day & Night Tablets

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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

- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty swallowing or breathing.
- Allergic reactions including skin rashes (which may be severe and include blistering or peeling of the skin) and itching
- 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. Stop using this medicine if you develop these symptoms and contact your doctor or seek medical attention immediately.
- Hallucinations, paranoid delusions or fits.

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

- Breathing difficulties
- Trouble passing water (especially men with prostate problems)
- Unusual tiredness, unexpected bruising or bleeding and getting more infections (such as colds) than normal. A fast or irregular heartbeat or an increased awareness of your heartbeat (palpitations).

Other effects which may occur include:

- Having trouble getting to sleep
- Anxiety, difficulty sleeping, nervousness, irritability, agitation, feeling jittery, feelings of extreme happiness
- Confusion
- Drowsiness, dizziness, blurred vision, headache
- Ringing of the ears
- Loss of coordination
- Tremors
- Tingling or numbness in the hands or feet
- Dry mouth and nose
- Feeling sick or being sick
- Pain when passing water
- Constipation, diarrhoea, stomach pain
- Indigestion
- High blood pressure or low blood pressure
- Chest discomfort
- Problems with your liver function that may show up on blood tests

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2.

Tel: +353 1 6764971, Fax: +353 1 6762517.

Website: www.hpra.ie e-mail: medsafety@hpra.ie

5. How to store Benylin Day & Night Tablets

Do not store above 25°C.

Store in the original package.

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 label and 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. Contents of the pack and other information

What Benylin Day & Night Tablets contain

The active substances are:

Day Tablets – paracetamol 500mg and pseudoephedrine hydrochloride 60mg

Night Tablets – paracetamol 500mg and diphenhydramine hydrochloride 25mg.

The other ingredients are:

Day Tablets (White) – Pregelatinised maize starch, povidone, crospovidone, stearic acid, microcrystalline cellulose, croscarmellose sodium and magnesium stearate.

Night Tablets (Blue) – Microcrystalline cellulose, maize starch, sodium starch glycollate, pregelatinised maize starch, hydroxypropylcellulose, croscarmellose sodium, stearic acid and magnesium stearate. Film-coating (Blue tablet only) - hypromellose, indigo carmine (E132), titanium dioxide (E171) and propylene glycol.

What Benylin Day & Night Tablets looks like and contents of the pack

Benylin Day & Night Tablets are available in packs containing 12 white oblong day-time tablets scored on one side, 'A7C' engraved on both sides of the score.

The score is to allow breaking for ease of swallowing.

And 4 blue, odourless, round night-time tablets.

Pack size: 16 tablets

Manufacturer

Manufactured by: Janssen-Cilag, 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: 1151/264/001

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Is this leaflet hard to see or read?**

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(Regulatory)**