

Package leaflet: Information for the patient

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 is and what it is used for

Benylin Day and Night Tablets 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 hydrochloride (a decongestant which unblocks stuffy noses) and are for daytime use.

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

Benylin Day & Night is indicated for the short-term symptomatic treatment of nasal and sinus congestion associated with symptoms of cold and flu such as pain, headache and/or fever only in combination with bedtime symptoms which are causing difficulty in getting to sleep.

This medicine is for use in adults and adolescents over 15 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 (hypertension)
- If you have an overactive thyroid
- 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 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.

Warnings and precautions

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 50 kg, suffer from chronic malnutrition or are dehydrated.
- If have a heart rhythm problem known as 'long QT interval'
- If you have a heart condition or high blood pressure.
- If you have a thyroid disease
- If you have glaucoma (increased pressure in the eye)
- If you have a breathing problem

Reduction of blood flow to your optic nerve may occur with Benylin Day & Night Tablets. If you develop sudden loss of vision, stop taking Benylin Day & Night Tablets and contact your doctor or seek medical attention immediately. See section 4.

During treatment with Benylin Day & Night Tablets, tell your doctor straight away:

- 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.
- 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).

One of the active ingredients in Benylin Day & Night tablets, pseudoephedrine, has the potential to be abused and large doses of pseudoephedrine can be toxic. Continuous use may lead to taking more Benylin Day 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).

Sudden abdominal pain or rectal bleeding may occur with Benylin Day & Night Tablets, due to inflammation of the colon (ischemic colitis). If you develop these gastro- intestinal symptoms, stop taking Benylin Day & Night Tablets and contact your doctor or seek medical attention immediately. See section 4.

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 Day & Night 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).

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 while using any other paracetamol containing products, diphenhydramine containing products (including on the skin) or other 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)
- Moclobemide (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, bretylium, reserpine and betanidine)
- 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)
- Anticholinergic drugs e.g. atropine
- Anticonvulsants (drugs used to treat epilepsy)
- Sedatives and tranquilizers (drugs used to calm and induce sleep)
- Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).
- Medicines which affect the heart rhythm (prolonging the QT interval). These include:
 - class IA and III anti-arrhythmic drugs
 - some antibiotics
 - anti-malaria drugs
 - neuroleptics
 - Water tablets (diuretics) that help you regularly produce urine (these may result in low potassium levels)
- 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.

Benylin Day & Night Tablets contain sodium.

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially ‘sodium-free’.

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 adolescents aged 15 years and over

Age	Dose
Adults and adolescents aged 15 years and over	<p>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)</p> <p>Night time 1 blue tablet to be taken at night</p>

- 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.
- Patients should seek medical advice if symptoms persist for more than 3 days or worsen.
- Contain paracetamol. Do not exceed stated dose.

The effective daily dose should not exceed 2g/day of paracetamol in the following situations unless advised by a doctor:

- Weight less than 50kg
- Liver impairment
- Chronic alcoholism
- Dehydration
- Chronic malnutrition

The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

Use in children and adolescents

This medicine is not recommended for children and adolescents under 15 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 delayed, serious 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 help:

- Serious conditions affecting blood vessels in the brain known as posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS). Symptoms include:

- sudden onset of severe headache
- nausea
- feeling sick
- confusion
- seizures
- vomiting
- visual disturbances
- Allergic reactions including skin rashes (which may be severe and include blistering or peeling of the skin) and itching
- 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 severe headache, nausea, vomiting or visual disturbances which may be symptoms of conditions known as Posterior Reversible Encephalopathy Syndrome (PRES) or Reversible Cerebral Vasoconstriction Syndrome (RCVS).

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
- There have been rare reports of blood disorders although these were not necessarily related to paracetamol
- Reduced blood flow to the optic nerve (Ischaemic optic neuropathy)

Other effects which may occur include:

- Having trouble getting to sleep
- Anxiety, nervousness, irritability, agitation
- Confusion
- Mood changes
- Drowsiness, dizziness, blurred vision, headache
- Ringing of the ears
- Loss of coordination
- Fits
- Shaking
- Tingling or numbness in the hands or feet
- Dry mouth, nose and throat
- Upset stomach
- Feeling sick or being sick
- Constipation or diarrhoea
- Indigestion
- High blood pressure or low blood pressure
- Chest discomfort
- Changes in your heart beat or heart rate
- Problems with your liver function that may show up on blood tests
- Inflammation of the colon due to insufficient blood supply (ischemic colitis)
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via HPRA Pharmacovigilance www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

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. 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:
In the white Day Tablets – 500mg paracetamol and 60mg pseudoephedrine hydrochloride per tablet
In the blue Night Tablets – 500mg paracetamol and 25mg diphenhydramine hydrochloride per film-coated tablet
- The 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 glycollate, pregelatinised maize starch, hydroxypropylcellulose, croscarmellose sodium, stearic acid, magnesium stearate and are coated with methylcellulose (methocel E5), Opaspray M-IF-4315B containing 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 come in a PVC/PVDC/Aluminium foil blister pack in a carton containing 12 white oblong “day-time” tablets with a dissecting score line on one side and ‘A7C’ engraved on both sides of the line and 4 blue round “night-time” film-coated tablets.

Marketing Authorisation Holder and Manufacturer

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, F27 100 Val de Reuil, France.

This medicinal product is authorised in the Member States of the EEA under the following names:

Bulgaria	Olygrip Day and Night Tablets
Cyprus	Hexaflu Day & Night
Ireland	Benylin Day And Night Tablets
Greece	Hexaflu Day & Night
Romania	Olygrip Day and Night comprimate

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