

PATIENT INFORMATION LEAFLET



Night

Paracetamol + Diphenhydramine

Please read right through this leaflet before you start using this medicine.

This medicine is available without prescription, but you still need to use Panadol Night carefully to get the best results from them.

- Keep this leaflet you may need to read it again.
- If you have any questions, or if there is anything you do not understand, ask your pharmacist.

In this leaflet:

1. What Panadol Night does
2. Check before you take Panadol Night
3. How to take Panadol Night
4. Possible side effects
5. How to store Panadol Night
6. Further information

1. What Panadol Night does

Panadol Night is used for the relief of bedtime pain. It is suitable for pain such as headache, migraine, backache, rheumatic and muscle pain, toothache or period pain.

The active ingredients are paracetamol and diphenhydramine hydrochloride. Paracetamol is a painkiller and diphenhydramine hydrochloride is an antihistamine that causes sleepiness or drowsiness making it useful when pain is keeping you awake.

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2. Check before you take Panadol Night



Do not take Panadol Night:

- if you have ever had an **allergic reaction** to paracetamol, diphenhydramine hydrochloride or to any of the other ingredients (listed in Section 6)
- if you have **porphyria** (too much of the pigment called porphyrin which may discolour the urine)
- if you have taken another medicine containing **paracetamol in the last 4 hours**.

Contains paracetamol.

Do not take with any other antihistamine-containing products, including those used on your skin or in cough and cold medicines.



Ask your doctor before you take this medicine:

- if you have **liver** or **kidney** problems, including **alcoholic liver disease**, are **underweight** or **malnourished** or **regularly drink alcohol**. You may need to **avoid** using this product altogether or **limit the amount** of paracetamol that you take.
- if you have **epilepsy**, or **seizure disorders**
- if you have an **obstruction in your stomach or gut** (for example, because of an ulcer)
- if you experience **difficulty passing urine**
- if you have narrow-angle **glaucoma** (raised pressure in the eye)
- if you have an **enlarged prostate**
- if you have **myasthenia gravis**
- if you have **asthma**, **bronchitis** or Chronic Obstructive Pulmonary Disease (**COPD**)
- if you have been told by your doctor that you have an **intolerance to some sugars**.

Contact a doctor immediately if you get a combination of these symptoms.

During treatment with Panadol Night, tell your doctor straight away:

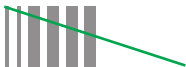
If you have severe infection or severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition 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), being sick (vomiting) and loss of appetite.



Take special care with Panadol Night

- **Do not drive or operate machinery.** Panadol Night is intended to produce sleepiness or drowsiness soon after the dose is taken.
- **Do not drink alcohol** while using Panadol Night

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If you are taking other medicines

Talk to your doctor or pharmacist before taking these tablets if you are taking any prescribed medicines; particularly **monoamine oxidase inhibitors** (MAOIs) in the last 2 weeks or **tricyclic antidepressants** (prescribed for **depression**); **atropine**; **beta blockers** (to treat heart problems); **metoclopramide** or **domperidone** (for **nausea** or **vomiting**); **metoprolol** or **venlafaxine**; **colestyramine** (to lower **blood cholesterol**); medicines for **stomach cramps** (e.g. **dicycloverine**) or **travel sickness** (e.g. **hyoscine**); medicines to treat **anxiety** or to help you **sleep**; medicines that make you **drowsy** or give you a **dry mouth**; **blood thinning drugs** (anticoagulants e.g. **warfarin**) or painkillers (e.g. **codeine**); **flucloxacillin** (antibiotic), due to a serious risk of blood and fluid abnormality (called **metabolic acidosis**) that must have urgent treatment (see section 2).



Pregnancy and breast feeding

Do not take Panadol Night if you are **pregnant** or **breast feeding**.

3. How to take Panadol Night



Adults (including the elderly) and children aged 16 years and over:
Swallow 2 tablets with water, 20 minutes before you go to bed.
Do not take more than 2 tablets in 24 hours.



- **Do not take Panadol Night if you have already taken 4 doses of a paracetamol-containing product during the day.**
- **Do not take more than the recommended dose.**
- **Do not take if you are under 16 years.**

If you take too many tablets

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.

Do not take Panadol Night for more than one week

If your bedtime pain carries on for more than one week, or if your headache becomes persistent, **see your doctor**.

4. Possible side effects

Like all medicines, Panadol Night can have side effects, but not everybody gets them. If you are a carer of an elderly patient with confusion, this medicine should not be given. Very rare cases of serious skin reactions have been reported.

Stop taking this medicine and **tell your doctor immediately** if you experience:

- **Allergic reactions** which may be severe such as skin rash and itching sometimes with swelling of the mouth or face or shortness of breath
- **Chest tightness** or **thickening of phlegm**
- **Difficulty in passing urine, headaches**

- **Upset stomach, nausea** or **vomiting**
- **Breathing problems.** These are more likely if you have experienced them before when taking other painkillers (such as ibuprofen and aspirin)
- **Seizures** or **difficulty of muscle coordination**
- Changes in **heart rhythm**
- Unexplained **bruising** or **bleeding**
- Reoccurring **fevers** or **infections**
- **Nausea, sudden weight loss, loss of appetite** and **yellowing of the eyes and skin.**

When using this product you may experience:

- Drowsiness, sedation, unsteadiness, dizziness, tiredness, blurred vision, or difficulty concentrating
- Dry mouth
- Feeling restless or excitable, confusion
- Tingling sensation in the skin
- Muscle twitching
- 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 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. How to store Panadol Night

Keep out of the sight and reach of children.

Do not use this medicine after the 'EXP' date shown on the pack.
Store below 25°C in a dry place.

6. Further information

Active ingredients: Each tablet contains Paracetamol 500 mg and Diphenhydramine Hydrochloride 25 mg. **Other ingredients** Maize starch, starch pre-gelatinised, potassium sorbate (E 202), povidone, purified talc, stearic acid, hypromellose (E 464), titanium dioxide (E 171), lactose monohydrate, macrogol 400, triacetin, brilliant blue FCF (E 133), indigo carmine (E 132) and carnauba wax.

Packs of Panadol Night contain 20 film-coated tablets.

The marketing authorisation holder is Haleon UK Trading Limited, The Heights, Weybridge, KT13 0NY, U.K. and all enquiries should be sent to this address.

The manufacturer is Haleon Ireland Dungarvan Limited, Knockbrack, Dungarvan, Co. Waterford, X35 RY76, Ireland or Omega Pharma Manufacturing GmbH & Co. KG, Benzstraße 25, 71083, Herrenberg, Germany.

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