

Panadol[®]

Night

Film-coated tablets Paracetamol 500mg, Diphenhydramine hydrochloride 25mg

PATIENT INFORMATION LEAFLET

Please read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to take Panadol Night carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms persist.
- If any of the side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Panadol Night is and what it is used for

Panadol Night tablets provide fast and effective relief of the fever, aches and pains associated with colds and flu, headaches, backache, rheumatic and muscle pains, period pains and toothache.

Panadol Night tablets contain paracetamol which is an analgesic (a pain killer which relieves aches and shivers) and antipyretic (it reduces body temperature when you have a fever) and diphenhydramine hydrochloride, an antihistamine which acts to relieve the symptoms of cold and 'flu (congestion).

Diphenhydramide hydrochloride may make you drowsy which is why Panadol Night should only be taken at bedtime.

2. Before you take Panadol Night



Do not take Panadol Night:

- If you are allergic to paracetamol or diphenhydramine hydrochloride or to any of the other ingredients listed in Section 6.
- With other products containing paracetamol.
- If you have a condition known as porphyria (too much of a pigment called porphyrin which may discolour the urine).
- If you have glaucoma (increased pressure in your eye).
- If you suffer from asthma, do not use during an attack.
- With other medicines called antihistamines including those used on your skin or in cough and cold medicines.
- If you are elderly and suffer from confusion.



Taking other medicines.

Please see your doctor before you take Panadol Night tablets if:

- You are taking metoclopramide or domperidone (used to treat nausea and vomiting) or cholestyramine (used to treat high cholesterol) or warfarin (used to thin the blood).
- You are taking any other medicines particularly tablets to help you sleep or pain killers or medicines for depression or anxiety, including venlafaxine, or tricyclic antidepressants, or are taking or have taken in the last two weeks monoamine oxidase inhibitors (MAOIs).
- You are taking metoprolol or atropine or medicines for stomach cramps or travel sickness which may give you dry mouth or blurred vision.



Take special care with Panadol Night if:

- You have severe liver or kidney problems, epilepsy, asthma, bronchitis or other breathing problems, bowel obstruction, difficulty passing urine or have prostate problems, heart or circulation problems, or myasthenia gravis (a disease with symptoms of muscle weakness and fatigue).
- You suffer from inherited sugar intolerance or sugar absorption problems.
- You are elderly- elderly people are more likely to experience possible side effects. Carers should be aware that this medicine should not be given to elderly patients with confusion.



Taking Panadol Night with food and drink:

Alcohol should not be taken with Panadol Night.



Pregnancy and breastfeeding:

Panadol Night tablets should not be taken when you are pregnant or breastfeeding unless your doctor tells you to.



Driving and using machines:

Panadol Night may cause drowsiness, dizziness, difficulty concentrating or blurred vision which means that you should not drive or operate machinery after taking the tablets. You should not take Panadol Night at the same time as other medicines containing antihistamines.



Important Information about some of the ingredients of Panadol Night:

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this product.

3. How to take Panadol Night



For bedtime use only.

Swallow Panadol Night tablets with water.

Adults (including the elderly) and children aged 12 years and over:

Take 2 tablets about 20 minutes before bedtime. Do not take more than 2 tablets per night. Do not take Panadol Night for more than 10 consecutive nights without consulting your doctor.

When taking Panadol Night at bedtime, you may take other tablets containing paracetamol during the day but do not take more than 4,000mg paracetamol (including this product) in any 24 hours with at least 4 hours between doses.

Not recommended for children under 12 years except under medical advice.



- Do not exceed stated dose.
- If symptoms persist contact your doctor.
- Prolonged use except under medical supervision may be harmful.

If you take too many tablets

Immediate medical advice should be sought in the event of overdosage because of the risk of irreversible liver damage.

4. Possible side effects

Like all medicines, Panadol Night can cause side effects, although not everybody gets them.

Stop using this product and tell your doctor immediately if you experience any of the following:

Very Rare (affects less than 1 in 10,000 people)

- unexplained bruising or bleeding.
- allergic reactions such as skin rash or itching, sometimes with breathing problems or swelling of the lips, tongue, throat or face.
- skin rash or peeling, swelling or mouth ulcers.

- previous allergic reactions to aspirin or non-steroidal anti-inflammatories, and you experience a similar reaction with this product.
- changes in blood tests that measure the function of your liver.

Common (affects between 1 in 10 and 1 in 100 people)

- fatigue.
- sedation, drowsiness, difficulty concentrating, unsteadiness, dizziness.
- dry mouth.

Other side effects may include: confusion, restlessness, headache, seizure (fits), tingling sensation in the skin, difficulty in making small movements, blurred vision, raised or abnormal heart beat, thickening of phlegm, indigestion or upset stomach, nausea, vomiting, muscle twitching, difficulty passing water.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Panadol Night

Do not store above 25°C.

Store in a dry place and in the original packaging, to protect from light.

Do not use this medicine after the expiry date (EXP) which is stated on the outer carton and blister. The expiry date refers to the last day of that month.

Keep out of the sight and reach of children.

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

Each tablet contains: Paracetamol 500mg, Diphenhydramine hydrochloride 25mg.

The tablets also contain: maize starch, pregelatinised starch, povidone K25, potassium sorbate, talc, stearic acid. The film coat contains: hypromellose, titanium dioxide (E171), lactose monohydrate, macrogol 400, triacetin, brilliant blue FCF aluminium lake (E133), indigo carmine aluminium lake (E132). The polishing agent: carnauba wax.

Panadol Night tablets are blue, capsule shaped, film-coated tablets, marked with PM on one side.

Panadol Night contains 20 tablets in blister strips. Two blister strips are contained in a carton.

The Product Authorisation holder is:

GlaxoSmithKline Consumer Healthcare (Ireland) Limited, Stonemasons Way, Rathfarnham, Dublin 16 and all enquiries should be sent to this address.

Manufactured by:

Omega Pharma Manufacturing GmbH & Co. KG, Benzstr. 25, 71083 Herrenberg, Germany.

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