

Information for the user

Night Nurse[®]
capsules



Paracetamol 500mg
Promethazine hydrochloride 10mg
Dextromethorphan hydrobromide 7.5mg

Please read right through this leaflet before you start using this medicine.
This medicine is available without prescription, but you still need to use Night Nurse Capsules carefully to get the best results from them.

- Keep this leaflet, you may need to read it again.
- If you have any further questions, ask your pharmacist.

In this leaflet:

1. What Night Nurse Capsules are and what they are used for
2. Check before you take Night Nurse Capsules
3. How to take Night Nurse Capsules
4. Possible side effects
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1. What Night Nurse Capsules are and what they are used for

Night Nurse Capsules are used for the night time relief of the symptoms of chills, cold and 'flu including headache, shivers, aches and pains, sore throat, runny nose and dry tickly cough. Night Nurse Capsules contain three active ingredients. Paracetamol is a painkiller and reduces your temperature when you have a fever. Promethazine hydrochloride is an antihistamine which dries up a runny nose to allow easy breathing and aids restful sleep. Dextromethorphan hydrobromide is a cough suppressant that helps relieve dry or tickly coughs.

2. Check before you take Night Nurse Capsules



Do not take Night Nurse Capsules:

- if you have ever had an allergic reaction to paracetamol, promethazine hydrochloride, dextromethorphan hydrobromide or any of the other ingredients (listed in Section 6).
- if you have severe liver or kidney problems.
- if you have pneumonia, asthma or severe respiratory problems.
- if you are taking monoamine oxidase inhibitors (MAOIs) prescribed for depression.
- if you are having a pregnancy test carried out on your urine.
- if you are under 16 years.

Contains Paracetamol.

Do not take with any other paracetamol-containing products.

Do not take with other cough or cold medicines, or any other products containing decongestants or antihistamines, including those used on your skin.



Talk to your doctor

- if you have a persistent or chronic cough such as occurs with smoking, asthma or emphysema or other breathing problems, or if the cough is accompanied by excessive phlegm (mucus).
- if you have been told by your doctor that you have an intolerance to some sugars, as this product contains lactose.
- if you have epilepsy, enlarged prostate, heart problems, glaucoma, asthma, bronchitis or other similar respiratory problems or urinary retention (difficulty in passing urine).
- If you have a severe infection as this may increase the risk of metabolic acidosis.
- Signs of metabolic acidosis include:
 - deep, rapid, difficult breathing
 - feeling sick (nausea), being sick (vomiting)
 - loss of appetite

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



Take special care with Night Nurse Capsules

- Do not drive or operate machinery. Night Nurse Capsules may cause drowsiness.
- Do not drink alcohol while using Night Nurse Capsules.



If you are taking other medicines

Please talk to your doctor or pharmacist before taking these capsules if you are taking any prescribed medicines; particularly metoclopramide or domperidone (for nausea [feeling sick] or vomiting [being sick]); colestyramine (to lower blood cholesterol); medicines to treat depression (e.g. a selective serotonin reuptake inhibitor (SSRI) or tricyclic antidepressant); medicines which make you drowsy, or which are used to treat anxiety, or help you sleep; medicines which give you a dry mouth or blurred vision (sometimes called anti-cholinergics) e.g. atropine or antidepressants. If you take blood thinning drugs (anticoagulants e.g. warfarin) and you need to take a pain reliever on a daily basis, talk to your doctor because of the risk of bleeding. But you can still take occasional doses of Night Nurse Capsules at the same time as anticoagulants.

Important information about some of the ingredients of Night Nurse Capsules:

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



Pregnancy and breastfeeding

Do not take Night Nurse Capsules if you are pregnant or breastfeeding, unless your doctor advises you to.

3. How to take Night Nurse Capsules



Swallow Night Nurse Capsules with water.

Adults (including the elderly) aged 16 years and over:

Take 2 capsules just before bedtime.



- Do not give to children under 16 years, unless your doctor recommends.
- Do not exceed the stated dose.
- Please see your doctor if your symptoms do not improve, or if you develop a high temperature, skin rash or persistent headache. Prolonged use may be harmful.
- Do not take Night Nurse Capsules if you have already taken 4 doses (4000 mg) of a paracetamol-containing product (including this product) in any 24 hour period. If in doubt consult your doctor or pharmacist.
- If during the day you take any other medicine containing paracetamol, the dose should be reduced to three times a day with the last dose at least 4 hours before Night Nurse Capsules are taken at bedtime.
- You should only use one dose of Night Nurse per night.
- Do not take for more than 7 nights.

Carers should be aware that this medicine should not be given to elderly patients with confusion. The elderly are more likely to develop adverse effects, including confusion, with this medicine.

If you take too many capsules

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.

4. Possible side effects

Like all medicines, Night Nurse Capsules can have side effects, but not everybody gets them. Children and the elderly may be more likely to experience side effects with this medicine.

Common side effects:

You may experience drowsiness, dizziness, movement difficulties, restlessness, unsteadiness, difficulty concentrating, dry mouth, headache or blurred vision.

Stop taking this medicine and tell your doctor immediately if you experience any of the following rare side effects:

- Very rare cases of serious skin reactions have been reported, sometimes with breathing problems or swelling of the lips, tongue or face.

- Skin rash or peeling, or mouth ulcers.
- If you have previously experienced breathing problems with aspirin or non-steroidal anti-inflammatories, you may experience a similar reaction with this product.
- Unexplained bruising and bleeding.
- Some or all of the following symptoms: confusion, feeling restless, sweating, shaking, shivering, sudden jerks of the muscles or increased blood pressure.
- Difficulty in passing urine.

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 Email: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Night Nurse Capsules

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date (EXP) shown on the carton and blister strips. The expiry date refers to the last day of that month. Do not store above 25°C. Store in the original package in order to protect from light.

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

Active ingredients Paracetamol 500mg, Promethazine Hydrochloride 10mg and Dextromethorphan Hydrobromide 7.5mg.

Other ingredients Lactose anhydrous, dimeticone, colloidal anhydrous silica, gelatin and colours patent blue V (E 131), quinoline yellow (E 104), titanium dioxide (E 171) and printing ink (containing shellac, isopropyl alcohol, iron oxide black (E 172), propylene glycol (E 1520), ammonium hydroxide (E 527) and n-butyl alcohol).

Night Nurse Capsules are hard gelatin capsules with a bright green cap and white body, printed with 'Night Nurse' on both halves. They are available in packs of 10 hard capsules.

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

The manufacturer is Wrafton Laboratories Ltd., Wrafton, Braunton, North Devon, EX33 2DL, United Kingdom.

This leaflet was last revised in January 2015.

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