

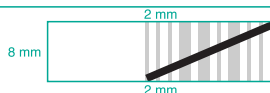
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**Paracetamol, Promethazine, Dextromethorphan**

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 carefully to get the best results from it.

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

## 1. What Night Nurse does

Night Nurse is used for the night-time relief of the major symptoms of colds, chills and flu. The medicine contains 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 and aids restful sleep. Dextromethorphan hydrobromide is a cough suppressant that helps relieve dry or tickly coughs. Night Nurse also helps to relieve a sore throat.

## 2. Check before you take Night Nurse

Contains paracetamol.

Taking too much paracetamol can cause serious harm to your liver. Do not take anything else containing paracetamol within four hours of taking this product. Do not take with other antihistamine-containing preparations, including topical antihistamines and cough and cold medicines.

### Do not take Night Nurse:

- 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 a chest infection, worsening asthma or severe respiratory problems.
- if you are taking or have taken monoamine oxidase inhibitors (MAOIs) prescribed for depression in the last two weeks.

### Take special care with Night Nurse:

- This medicine can lead to **dependence**. Therefore, the treatment should be of **short duration**.
- **Do not drink alcohol** while using Night Nurse.
- Night Nurse contains 18% v/v ethanol (alcohol), i.e. up to 2.9 g per dose, equivalent to 72 ml beer, 30 ml wine per dose. This could be harmful if you suffer from **alcoholism**. This should also be considered if you are **pregnant or breast-feeding**, in **children and high-risk groups** such as patients with **liver disease or epilepsy**.
- If your symptoms are accompanied by a high temperature, skin rash or persistent headache, **see your doctor**.
- This medicine may affect **pregnancy tests** based on urine samples, to give false results.

### Driving and operating machinery

This medicine can affect your ability to drive as it may cause drowsiness, dizziness, difficulty concentrating, movement

difficulties or blurred vision. If affected **do not drive or operate machinery**.

- **Do not drive** while taking this medicine until you know how it affects you.
- It may be an offence to drive when taking this medicine.
- However, you would not be committing an offence if the medicine has been taken to treat a medical or dental problem, and you have taken it according to the information provided with the medicine, and it was not affecting your ability to drive safely.

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine. Details regarding a new driving offence concerning driving after drugs have been taken in the UK may be found here:

[www.gov.uk/drug-driving-law](http://www.gov.uk/drug-driving-law).

### Ask your doctor before you take this medicine:

- if you have **liver or kidney problems**.
- if you have **glaucoma, epilepsy, difficulty passing urine, or prostate problems**.
- if you have **chronic or persistent cough** accompanied by excessive phlegm or respiratory problems.
- if you have **diabetes mellitus**. Each 20 ml dose contains **12.8 g of glucose**.
- if you are on a **sodium-controlled diet**. Each 20 ml dose contains **37 mg of sodium**.
- if you are **elderly** and suffer from **confusion**.
- if you have a **severe infection**, are severely malnourished, severely underweight or are a chronic heavy alcohol user, 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
- if you are taking medicines such as certain **antidepressants** or **antipsychotics** as Night Nurse may interact with these medicines and you may experience **mental status changes** (e.g. agitation, hallucinations, coma), and other effects such as **body temperature above 38°C**, increase in **heart rate**, unstable **blood pressure**, and exaggeration of **reflexes, muscular rigidity, lack of coordination and/or gastrointestinal symptoms** (e.g. nausea, vomiting, diarrhoea). **Contact a doctor immediately** if you get a combination of these symptoms.
- are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.

Taking this medicine regularly, particularly for a long time, can lead to **addiction**. Only use this medicine as described in the leaflet. Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Speak to your doctor if you experience withdrawal symptoms.

### If you are taking other medicines

Please talk to your doctor or pharmacist before taking this medicine if you are taking any other medicines; particularly **metoclopramide or domperidone** (for nausea or vomiting); **colestyramine** (to lower blood cholesterol); medicines which give you **blurred vision, a dry mouth or make you drowsy**; **blood thinning drugs** (anticoagulants e.g. warfarin); **quinidine or amiodarone** (to control your heart rhythm); medicines for **anxiety or depression** (e.g. selective serotonin reuptake inhibitor (SSRI) or tricyclic antidepressant) or to **help you sleep**.

You should also tell your doctor or pharmacist:

- if you have abused drugs or other substances in the past.
- if you have specific metabolism characteristics (slow metabolizer of CYP2D6).

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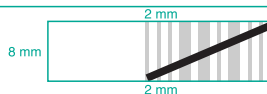
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## ! Pregnancy and breast feeding

Do not take Night Nurse if you are pregnant or breast-feeding.

## 3. How to take Night Nurse

✓ For oral use only. Adults and children aged 16 years and over: Fill the measuring cup to the 20 ml mark. Take one 20 ml dose (four teaspoonfuls) at bedtime only.

- ✓
  - Do not take Night Nurse 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.
  - Only take one dose of Night Nurse per night.
  - Do not take more than the recommended dose.
  - Only use Night Nurse for the shortest period of time necessary.
  - Do not take for more than 3 days.
  - Do not take if you are under 16 years.

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 much

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. You may experience the following symptoms: nausea and vomiting, involuntary muscle contractions, agitation, confusion, somnolence, disturbances in consciousness, involuntary and rapid eye movements, cardiac disorders (rapid heart beating), coordination disorders, psychosis with visual hallucinations, and hyperexcitability. Other symptoms in case of massive overdose may be: coma, severe breathing problems, and convulsions.

Contact your doctor or hospital straight away if you experience any of the above symptoms.

## 4. Possible side effects

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

### The following effects may occur:

- Drowsiness, dizziness, blurred vision, difficulty concentrating, unsteadiness, clumsiness, headache, dry mouth.

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

- Allergic reactions which may be severe such as skin rash, itching sometimes with swelling of the mouth or face or shortness of breath.
- Skin rash or peeling or mouth ulcers.
- Breathing problems. These are more likely if you have experienced them before when taking other painkillers (such as ibuprofen and aspirin).
- Unexplained bruising and bleeding.
- Confusion, feeling restless, sweating, shaking, shivering, sudden jerks of muscles or increased blood pressure (these may be symptoms of serotonin syndrome).
- Difficulty passing urine.
- Nausea, vomiting, stomach ache, sudden weight loss, loss of appetite and yellowing of the eyes and skin.
- Restlessness, nervousness, feeling irritable, increased energy and sleep disturbances, which are more likely to affect children.

These effects are rare.

- Dependence and addiction (see section "How do I know if I am addicted?") - unknown frequency.

## Drug Withdrawal

When you stop taking Night Nurse, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

### How do I know if I am addicted?

If you notice any of the following signs whilst taking Night Nurse, it could be a sign that you have become addicted.

- You need to take the medicine for longer than advised.
- You feel you need to use more than the recommended dose.
- You are using the medicine for reasons other than those indicated.
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again.

If you notice any of these signs, it is important you talk to your doctor or pharmacist.

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](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Night Nurse

Keep out of the sight and reach of children.

Do not take this medicine after the 'EXP' date shown on the pack.

## 6. Further information

**Active ingredients** Each 20 ml dose contains Paracetamol 1000 mg, Promethazine Hydrochloride 20 mg, Dextromethorphan Hydrobromide 15 mg.

**Other ingredients** Liquid glucose, ethanol (alcohol), macrogol 300, sodium cyclamate, acesulfame K, sodium citrate, ascorbic acid, disodium edentate, medicated flavour liquid, colours quinoline yellow (E 104) and patent blue V (E 131) and water.

This bottle contains 160 ml.

The marketing authorisation holder is GlaxoSmithKline Consumer Healthcare (UK) Trading Limited, Brentford, TW8 9GS, U.K. and all enquiries should be sent to this address.

The manufacturer is Omega Pharma Manufacturing GmbH & Co Benzstrasse 25, D-71083, Herrenberg, Germany.

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