

Package leaflet: Information for the user

Night Nurse Cold Remedy Oral Solution

Paracetamol 1000mg/20ml, Promethazine hydrochloride 20mg/20ml, Dextromethorphan hydrobromide 15mg/20ml

**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, pharmacist or nurse have 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, pharmacist or nurse. 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.

**What is in this leaflet:**

1. What Night Nurse Cold Remedy Oral Solution is and what it is used for
2. What you need to know before you take Night Nurse Cold Remedy
3. How to take Night Nurse Cold Remedy
4. Possible side effects
5. How to store Night Nurse Cold Remedy
6. Contents of the pack and other information

**1. What Night Nurse Cold Remedy is and what it is used for**

**Night Nurse Cold Remedy is 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 Cold Remedy 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. The liquid glucose syrup helps relieve a sore throat as well.

**2. What you need to know before you take Night Nurse Cold Remedy  
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 cough or cold medicines, or any other products containing antihistamines, including those use on your skin. Do not drink alcohol while using Night Nurse Cold Remedy.**

**[X] 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 liver or kidney problems.**
- **if you have pneumonia, asthma or severe respiratory problems.**

- if you are taking **antihistamines** or **tricyclic antidepressants** (e.g. imipramine or amitriptyline) or have taken **monoamine oxidase inhibitors (MAOIs)** prescribed for **depression** in the last two weeks.
- if you are **under 16 years**.

## [!] Warnings and Precautions

### Take special care with Night Nurse Capsules

- This medicine can lead to **dependence**. Therefore the treatment should be of **short duration**.
- This medicine may affect pregnancy tests based on urine samples, to give false results.
- If you are elderly as you may be more likely to experience side effects.

## [+] Talk to your doctor

- if you 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 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 liquid glucose.
- if you have epilepsy, enlarged prostate, urinary retention (difficulty in passing urine), heart problems, glaucoma, asthma, bronchitis or other similar respiratory problems.
- medical advice should be sought if symptoms persist, or are accompanied by high fever, skin rash or persistent headache.
- 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
- 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.

## [!] Other medicines and Night Nurse Capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other 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 anticholinergics) 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 Cold Remedy at the same time as anticoagulants.

Please inform your doctor or pharmacist if you are taking **flucloxacillin (antibiotic)**, due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.

#### [!] **Taking with food, drink and alcohol**

- This medicinal product contains 18.0% v/v ethanol (alcohol), i.e. up to 2840mg per dose, equivalent to 72ml beer, 30ml wine per dose. Harmful for those suffering from alcoholism. To be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease, or epilepsy.
- Do not drink alcohol while using Night Nurse Cold Remedy.

#### [!] **Pregnancy and breastfeeding**

- 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. You should use the lowest possible dose that reduces your symptoms and use it for the shortest time possible. Contact your doctor or pharmacist if your symptoms are not reduced or if you need to take the medicine more often.

#### [!] **Driving and using machines**

- 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

#### [!] **Important information about some of the ingredients of Night Nurse Capsules:**

- Each 20ml dose contains 37mg of sodium. To be taken into consideration by those on a controlled sodium diet.
- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. Contains 12.8g of glucose per dose. This should be taken into account in patients with diabetes mellitus.

### 3. **How to take Night Nurse Cold Remedy**



**Adults (including the elderly) aged 16 years and over:** Fill the measuring cup to the 20ml mark (four 5ml spoonfuls) and take just before going to bed.

[!]

- **Do not give to children under 16 years.**
- **You should only use one dose of Night Nurse Cold Remedy each night.**
- **Do not take for more than 7 nights. • Do not take Night Nurse Cold Remedy if you have already taken 4000 mg of a paracetamol- containing product (including this product) in any 24 hour period. If in doubt consult your doctor or pharmacist.**
- **Do not exceed the stated dose.**
- **Always use the lowest effective dose to relieve your symptoms.**

- **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.**
- **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 more Night Nurse Cold Remedy 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. 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 maybe: 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 Cold Remedy can have side effects, but not everybody gets them. Children and the elderly may be more likely to experience side effects with this medicine.

**If you have any of the following symptoms after taking Night Nurse Cold Remedy, STOP taking the medicine and tell your doctor immediately:**

##### **Possible side effects:**

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

**Very Common** (may affect more than 1 in 10 people)

- Drowsiness.

**Common** (may affect up to 1 in 10 people)

- Dizziness, movement difficulties, restlessness, unsteadiness, difficulty concentrating, dry mouth, headache or blurred vision.

**Very Rare** (may affect up to 1 in 10,000 people)

- You may experience a 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.
- You may experience unexplained bruising and bleeding.
- Changes in tests which measure the function of your liver.

##### **The following side effects may also occur:**

- You may experience difficulty passing urine.
- You may experience some or all of the following symptoms: confusion, feeling restless, sweating, shaking, shivering, sudden jerks of the muscles or increased blood pressure - these may be symptoms of serotonin syndrome.
- Gastro-intestinal disturbances such as nausea, vomiting or abdominal discomfort.
- Photosensitivity or skin rash.
- Confusion, disorientation or paradoxical excitation e.g. increased energy, irritability, restlessness, nervousness, sleep disturbance.

Night Nurse Cold Remedy may affect the results of tests which relate to your immune system.

**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, Website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Night Nurse Cold Remedy****Keep out of the sight and reach of children.**

Do not store above 25°C. Store in the original package in order to protect from light.

Do not use this medicine after the 'EXP' date shown on the bottle label and carton.

The 'EXP' 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 Night Nurse Cold Remedy contains**

**Active ingredients:** Each 20ml dose of oral solution contains Paracetamol 1000mg, Promethazine Hydrochloride 20mg and Dextromethorphan Hydrobromide 15mg.

**Other ingredients:** Liquid glucose, ethanol (alcohol), macrogol 300, sodium cyclamate, acesulfame K, sodium citrate, ascorbic acid, disodium edetate, medicated flavour liquid, colours quinoline yellow (E104) and patent blue V (E131) and purified water

**What Night Nurse Cold Remedy looks like and contents of the pack**

Night Cold Remedy is a dark green, clear, slightly viscous liquid with a characteristic minty and medicated odour and flavour. The product is packed in 160ml bottles.

**Marketing Authorisation Holder:** GlaxoSmithKline Consumer Healthcare (Ireland) Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24 and all enquiries should be sent to this address.

**Manufacturer:** Omega Pharma Manufacturing GmbH & Co Benzstrasse 25, D-71083, Herrenberg, Germany.

This leaflet was last revised in May 2022.

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