

# Night Nurse Cold Remedy

## Oral Solution

Paracetamol 1000mg/20ml

Promethazine Hydrochloride 20mg/20ml

Dextromethorphan Hydrobromide 15mg/20ml

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 Cold Remedy 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 Cold Remedy is and what it is used for
2. Check 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
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## 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 colds, chills and influenza including headache, shivers, aches and pains, sore throat, runny nose and dry, tickly cough.

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

## 2. Check before you take Night Nurse Cold Remedy

### Do not take Night Nurse Cold Remedy

- 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 if you have taken monoamine oxidase inhibitors (MAOIs) prescribed for depression in the last two weeks.
- if you are having a pregnancy test carried out on your urine.
- if you are under 16 years.

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.

Do not drink alcohol while using Night Nurse Cold Remedy.

## Warnings and precautions

### Take special care with Night Nurse Cold Remedy

- if you are elderly as you may be more likely to experience side effects.



### 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 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

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



### If you are taking other medicines

Please talk to your doctor or pharmacist before taking Night Nurse Cold Remedy if you are taking any prescribed medicines; particularly metoclopramide or domperidone (for nausea [feeling sick] or vomiting [being sick]); colestyramine (to lower blood cholesterol); antiarrhythmics (to treat heart rhythm problems) including quinidine and amiodarone; medicines to treat depression (e.g. a selective serotonin reuptake inhibitor (SSRI) such as fluoxetine or paroxetine or tricyclic antidepressant); antipsychotics including haloperidol and thiorizidine; 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, antidepressants or antihistamines. 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.



### 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.

## Pregnancy and breastfeeding

**Do not take** Night Nurse Cold Remedy if you are **pregnant** or **breastfeeding** unless your doctor advises you to.


## Driving and using machines

**Do not drive or operate machinery.** Night Nurse Cold Remedy may cause drowsiness.

## Important Information about some of the ingredients of Night Nurse Cold Remedy

- Each 20ml dose contains 37mg 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 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, unless your doctor tells you to.
- 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 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.
- 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.
- 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

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 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 (affects more than 1 in 10 people)

- Drowsiness.

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

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

Very Rare (affects less than 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.
- 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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto: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 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.

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:** 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 oil, colours quinoline yellow (E104) and patent blue V (E131) and purified water.

Night Nurse 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.

**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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