

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 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 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. 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 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.



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 under 16 years.



Warnings and precautions

- 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 Cold Remedy


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); 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 thioridazine; 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

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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 breast-feeding

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 Cold Remedy

- 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 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 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. 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 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.

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

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