

Night Nurse capsules

Paracetamol 500mg

Promethazine hydrochloride 10mg

Dextromethorphan hydrobromide 7.5mg

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 Capsules are and what they are used for
2. What you need to know before you take Night Nurse Capsules
3. How to take Night Nurse Capsules
4. Possible side effects
5. How to store Night Nurse Capsules
6. Contents of the pack and other information

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. What you need to know before you take Night Nurse Capsules

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 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 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**.
- Do not drink alcohol while using Night Nurse Capsules.
- This medicine may affect pregnancy tests based on urine samples, to give false results.

Talk to your doctor before taking Night Nurse Capsules

- 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 epilepsy, enlarged prostate, heart problems, glaucoma, asthma, bronchitis or other similar respiratory problems or urinary retention (difficulty in passing urine).
- if you have any serious **heart problems**
- if you have any personal or family history of **heart disease**
- if you have an **irregular heartbeat**
- 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.

During treatment with Night Nurse Capsules, tell your doctor straight away

- if you have severe infection or severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include:

serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

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 anti-cholinergics) e.g. **atropine** or **antidepressants**; medicines that can affect your **heart rhythm**. 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.

You should also talk to your doctor if you have abused drugs or other substances in the past or if you have specific metabolism characteristics (slow metabolizer of CYP2D6).

Please inform your doctor or pharmacist if you are taking **flucloxacillin (antibiotic)**, due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

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 Capsules:

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

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.**
- **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.**

- **Do not take Night Nurse Capsules 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.**
- **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 more capsules 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 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.

If you have any of the following symptoms after taking Night Nurse Capsules, STOP taking this medicine and tell your doctor immediately.

- **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 - these may be symptoms of serotonin syndrome.
- Difficulty in passing urine.

Very common side effects (may affect more than 1 in 10 people):

- Drowsiness

Common side effects (may affect up to 1 in 10 people):

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

The following side effects may also occur. The frequency is not known (cannot be estimated from the available data):

- Abnormal electrical activity of the heart that affects its rhythm, including life-threatening rhythm disturbance
- A serious reaction with fever, rigid muscles, changing blood pressure and coma (neuroleptic malignant syndrome)
- Low levels of blood platelets (which can lead to bleeding and bruising)
- Restlessness
- Hallucinations
- Aggression
- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2).

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 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. Contents of the pack and other information

What Night Nurse Capsules contains

Active ingredients Paracetamol 500mg, Promethazine Hydrochloride 10mg and Dextromethorphan Hydrobromide 7.5mg. **Other ingredients** Lactose monohydrate, 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, iron oxide black (E 172), propylene glycol (E 1520), iron oxide yellow (E 172) and ammonium hydroxide (E 527).

What Night Nurse Capsules looks like and contents of the pack

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:

Haleon Ireland Limited, Clocherane, Dungarvan, Co. Waterford, Ireland.

Manufacturer

Haleon Alcala, S.A., Ctra. de Ajalvir, km. 2,500- 28806 Alcalá de Henares, Madrid - Spain

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PA 678/21/1