

Information for the user

Day Nurse capsules

Paracetamol 500mg
Pseudoephedrine hydrochloride 30mg
Pholcodine 5mg

Please read right through this leaflet before you start using this medicine.

This medicine is available without prescription, but you still need to use Day Nurse capsules carefully to get the best results from them.

- Keep this leaflet, you may need to read it again.
- If you have any further questions, ask your pharmacist.

In this leaflet:

1. What Day Nurse capsules are and what they are used for
2. Check before you take Day Nurse capsules
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4. Possible side effects
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1. What Day Nurse capsules are and what they are used for

Day Nurse capsules are used for the relief of the major symptoms of cold and flu including fever, pains, coughing and nasal congestion.

Day Nurse capsules contain three active ingredients. Paracetamol is a painkiller and reduces your temperature when you have a fever. Pseudoephedrine Hydrochloride is a decongestant that unblocks your nose and sinuses helping you to breathe more easily. Pholcodine is a cough suppressant that helps relieve dry or tickly coughs.

2. Check before you take Day Nurse capsules

[X] Do not take Day Nurse capsules:

- **if you have ever had an allergic reaction** to paracetamol, pseudoephedrine hydrochloride, pholcodine or any of the other ingredients (listed in Section 6).
- if you have ever developed a **severe skin rash** or skin that **peels, blisters or sores in the mouth** after taking Day Nurse capsules or other pseudoephedrine or pholcodine-containing medicinal products.

- if you have **high blood pressure** or **heart disease**.
- if you have **severe kidney disease**.
- if you have **difficulty breathing** or **lung problems**.
- if you are taking **appetite suppressants** or **stimulant drugs** called amphetamines (sometimes used to treat ADHD).
- if you have taken **monoamine oxidase inhibitors** (MAOIs) in the last two weeks.
- if you are **under 16 years**.
- if you are taking an antibiotic called **linezolid** or **furazolidone**.

Stop using this product and seek medical attention if you experience:

- **Sudden severe headache, nausea, vomiting** or **visual disturbances**.
- Sudden abdominal pain or blood in your stools.

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 any other flu, cold or decongestant product.

[+] **Warnings and Precautions**

Talk to your doctor if:

- you suffer from glutathione depletion due to metabolic deficiencies
- you have **liver** or **kidney** problems, 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.
- you have **asthma, long term cough** or a **cough which produces a lot of phlegm**.
- you have an **overactive thyroid gland, prostate gland enlargement, an irregular heartbeat, glaucoma, diabetes** or **phaeochromocytoma** (a tumour of the adrenal gland).
- you have **heart disease** or **high blood pressure**.
- if you are taking medicines to treat migraine e.g. medicines called ergot alkaloids.
- if you have serious mental health conditions
- if you are more than **60 years old**, as there is increased possibility of unwanted effects.

If you develop any of the below symptoms, stop taking Day Nurse capsules and contact your doctor or seek medical attention immediately (see section 4):

- sudden abdominal pain or rectal bleeding, due to inflammation of the colon (ischaemic colitis).
- sudden loss of vision caused by reduction of blood flow to the optic nerve.

- serious skin reactions, including acute generalized exanthematous pustulosis (AGEP), have been reported with the use of Day Nurse capsules. AGEP is a generalized, red, scaly rash with bumps under the skin and vesicles associated with a fever. It is most commonly located on the folds of the skin, the trunk and the upper limbs. The highest risk of serious skin reactions occurrence is especially during the first week of treatment.

[!] Take special care with Day Nurse capsules

- **Do not drink alcohol** while using Day Nurse capsules.
- The pseudoephedrine content in this product may induce a positive reaction during **anti-doping** control tests.
- Consult a doctor before use if you have a history of drug abuse; pholcodine is an opioid and addiction is observed with opioids as a class.
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- Cases of cross-reactivity with medicines called muscle relaxants used during anaesthesia, resulting in serious allergic reactions (anaphylaxis) have been reported in patients who have previously taken pholcodine. If are due to undergo anaesthesia at any time (such as for surgery), please inform your anaesthetist that you have taken pholcodine in the past

[!] Other medicines and Day Nurse capsules

Do not take Day Nurse capsules:

- with any other **paracetamol containing product**
- with any other **flu, cold** or **decongestant product**
- with **appetite suppressants** or **stimulant drugs**
- with any **tricyclic antidepressants**
- if you have taken **monoamine oxidase inhibitors (MAOIs)** in the **last two weeks**.

Tell your doctor, pharmacist or nurse if you are taking, have recently taken, or might take any other medicines; particularly:

- **digoxin** for **heart problems**
- **metoclopramide** or **domperidone** for **nausea** (feeling sick) or **vomiting** (being sick)
- **colestyramine** to **lower blood cholesterol**
- medicines for **high blood pressure**
- medicines that make you **drowsy**
- medicines for **anxiety** or **depression** or to **help you sleep**
- medicines to treat migraine e.g. medicines called **ergot alkaloids**
- if you are due to have an **operation**, as Day Nurse capsules may increase the risk of allergic reaction to some medicines used in general anaesthesia
- **blood thinning drugs (anticoagulants** e.g. **warfarin**) and you need to take a pain reliever on a daily basis because of the risk of bleeding. You can still take occasional doses of Day Nurse capsules at the same time as anticoagulants.

- **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.

[!] **Pregnancy and breastfeeding**

Do not take Day Nurse capsules if you are **pregnant** or **breast-feeding** unless **your doctor tells you to**. 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**

Do not drive or operate machinery if this medicine makes you feel dizzy.
Allura red is an azo dye and may cause allergic reactions, such as asthma.

3. How to take Day Nurse capsules

Check that the foil is not broken before use. Take during the day.

[tick] **Adults (including the elderly) and children over 16 years:**

Take 2 capsules with a drink of water every 4 to 6 hours up to a maximum of 8 capsules, or 4000mg paracetamol, in 24 hours

[!]

- Do not give to children under 16 years.
- Do not exceed the stated dose.
- Always use the lowest effective dose to relieve your symptoms.
- If symptoms persist, consult your doctor.
- Do not use this medicine for more than 7 days, unless your doctor agrees.

If you take too many capsules

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, Day Nurse capsules can have side effects, but not everybody gets them. Very rare cases of serious skin reactions have been reported.

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

Uncommon: may affect up to 1 in 100 people

- Difficulty passing urine. This is more likely to occur if you have an enlarged prostate gland.

Rare: may affect up to 1 in 1,000 people

- Skin rash or peeling or mouth ulcers
- Rapid heart rate or palpitations
- Blurred vision • Headache, ringing in the ears, irritability or shaking
- Diarrhoea, constipation or stomach pain.

Very rare: may affect up to 1 in 10,000 people

- Serious skin reactions, sometimes with breathing problems or swelling of the lips, tongue, throat or face
- Breathing problems. These are more likely if you have experienced them before when taking other painkillers (such as ibuprofen and aspirin)
- Unexplained bruising or bleeding
- Sudden weight loss, loss of appetite or yellowing of the skin and eyes.

Unknown:

- Sudden onset of fever, reddening of the skin, or many small pustules (possible symptoms of Acute Generalized Exanthematous Pustulosis - AGEP). This may occur within the first 2 days of treatment with Day Nurse. See section 2.
- Reduced blood flow to the optic nerve (Ischaemic optic neuropathy).

Stop using Day Nurse if you develop these symptoms and contact your doctor or seek medical attention immediately.

The following side effects may also occur:

Common: may affect up to 1 in 10 people

- Difficulty sleeping, irritability, nightmares or restlessness.
- Nausea and vomiting.
- Dry mouth
- Dizziness.

Rare: may affect up to 1 in 1,000 people

- Hallucinations (particularly in children) have been reported rarely.

Unknown:

- Headache, anxiety or tremor.
- Inflammation of the colon due to insufficient blood supply (ischaemic colitis)

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; e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Day 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.

The capsules should be stored in their original package to protect from moisture.

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: Paracetamol 500mg, Pseudoephedrine Hydrochloride 30mg and Pholcodine 5mg.

Other ingredients: Sodium starch glycollate, magnesium stearate (E572), sodium laurilsulfate, gelatin and colours quinoline yellow (E104), allura red (E129), titanium dioxide (E171) and printing ink (containing shellac, iron oxide black (E172), propylene glycol (E1520) and ammonium hydroxide (E527).

Allura red is an azo dye and may cause allergic reactions, such as asthma.

Day Nurse capsules are hard capsules with an orange cap and yellow body, printed with 'Day Nurse' in black ink. They are available in packs of 8, 10, 12, 16, 20 or 24 capsules. Not all pack sizes may be marketed.

The product authorisation holder is GlaxoSmithKline Consumer Healthcare (Ireland) Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland and all enquiries should be sent to this address.

The manufacturer is SmithKline Beecham S.A., Ctra. de Ajalvir, km. 2,500- 28806 Alcalá de Henares, Madrid - Spain.

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