

# ANVERSO (FRONT)

Information for the User

## Day & Night Nurse capsules



gsk

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 & Night 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 & Night Nurse Capsules do
2. Check before you take Day & Night Nurse Capsules
3. How to take Day & Night Nurse Capsules
4. Possible side effects
5. How to store Day & Night Nurse Capsules
6. Further information

### 1. What Day & Night Nurse Capsules do

Day & Night Nurse Capsules are used for the 24 hour relief of the major symptoms of colds, chills and influenza.

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

The night-time capsules also 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 and aids restful sleep. Dextromethorphan hydrobromide is a cough suppressant that helps relieve dry or tickly coughs.

### 2. Check before you take Day & 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 antihistamine-containing preparations, including topical antihistamines and cough and cold medicines.



Do not take Day & Night Nurse Capsules:

- if you have ever had an allergic reaction to paracetamol, pseudoephedrine hydrochloride, promethazine hydrochloride, pholcodine, dextromethorphan hydrobromide 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 or other related drugs
- if you have high blood pressure or heart disease
- if you have kidney problems or hyperexcitability
- if you have a chest infection, worsening asthma or severe respiratory 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) prescribed for depression in the last two weeks
- if you are taking an antibiotic called linezolid.
- sudden abdominal pain or rectal bleeding may occur with Day Nurse capsules, due to inflammation of the colon (ischaemic colitis). If you develop these gastro-intestinal symptoms, stop taking Day Nurse capsules and contact your doctor or seek medical attention immediately. See section 4.
- the pseudoephedrine content in this product may induce a positive reaction during anti-doping control tests.

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

- sudden abdominal pain or blood in your stools
- sudden severe headache accompanied by nausea, vomiting or a disturbance in vision.



Take special care with Day & Night Nurse Capsules

- This medicine can lead to dependence. Therefore, the treatment should be of short duration.
- Do not drink alcohol while using Day & Night Nurse Capsules.
- If your symptoms are accompanied by a high temperature, skin rash or persistent headache, see your doctor.
- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.
- If you are taking tricyclic antidepressants.

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

- if you develop fever, associated with generalised reddening of the skin and/or pustules
- sudden loss of vision caused by reduction of blood flow to the optic nerve
- serious skin reactions, including acute generalised exanthematous pustulosis (AGEP), have been reported with the use of Day Nurse. AGEP is a generalised, 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.



Driving and operating machinery

The orange/yellow (day-time) capsules may cause dizziness. If affected do not drive or operate machinery.

The green/white (night-time) capsules may cause drowsiness, dizziness, difficulty concentrating, movement difficulties or blurred vision. This can affect your ability to drive.

- Do not drive while taking this medicine until you know how it affects you.
- It may be an offence to drive when taking this medicine.
- However, you would not be committing an offence if the medicine has been taken to treat a medical or dental problem, and you have taken it according to the information provided with the medicine, and it was not affecting your ability to drive safely.

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine. Details regarding a new driving offence concerning driving after drugs have been taken in the UK may be found here:

[www.gov.uk/drug-driving-law](http://www.gov.uk/drug-driving-law).



Ask your doctor before taking this medicine:

- if you have liver or kidney problems.
- if you have been told by your doctor you have an intolerance to some sugars
- if you have an overactive thyroid gland, diabetes, an irregular heartbeat or pheochromocytoma (tumour of the adrenal gland).
- if you have glaucoma, epilepsy, difficulty passing urine, or prostate problems
- if you have asthma, long term cough or a cough which produces a lot of phlegm
- if you are due to have an operation
- if you are elderly and suffer from confusion.
- if you are skinny, underweight or regularly drink alcohol.
- if you are taking medicines to treat migraine e.g. medicines called ergot alkaloids.
- if you have a severe infection, are severely malnourished, severely underweight or are a chronic heavy alcohol user, 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.

Day-time Capsules only:

- have a history of drug abuse; pholcodine is an opioid and addiction is observed with opioids as a class.

Night-time Capsules only:

- are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.

Taking this medicine regularly, particularly for a long time, can lead to addiction. Only use this medicine as described in the leaflet. Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Speak to your doctor if you experience withdrawal symptoms.



If you are taking other medicines

Please talk to your doctor or pharmacist before taking these capsules if you are taking any prescribed medicines; particularly digoxin (for heart problems); metoclopramide or domperidone (for nausea or vomiting); colestyramine (to lower blood cholesterol); medicines for high blood pressure; medicines which give you blurred vision, a dry mouth or make you drowsy; blood thinning drugs (anticoagulants e.g. warfarin); quinidine or amiodarone (to control your heart rhythm); medicines for anxiety or depression (e.g. selective serotonin reuptake inhibitor (SSRI) or tricyclic antidepressant) or to help you sleep.

You should also tell your doctor or pharmacist:

- if you have abused drugs or other substances in the past.
- if you have specific metabolism characteristics (slow metabolizer of CYP2D6).



Pregnancy and breast-feeding

Do not take Day & Night Nurse Capsules if you are pregnant or breast-feeding.

### 3. How to take Day & Night Nurse Capsules



**DAYTIME Dosage:** to be taken with a drink of water every four hours, up to a maximum of 3 doses during the day, if needed.

**Adults aged 16 years and over:**

Two yellow/orange capsules.

**NIGHT-TIME Dosage:**

to be taken with a drink of water at bedtime.

**Adults aged 16 years and over:**

Two green/white capsules.



- After taking day-time capsules, wait at least 4 hours before taking the night-time capsules.
- Do not take night-time capsules if you have already taken 4 doses of a paracetamol-containing product during the day.
- Only take one dose of night-time capsule per night.
- Always use the lowest effective amount to relieve your symptoms.
- Do not take for more than 3 days.
- Do not take more than the recommended dose.
- Do not give to children under 16 years of age.
- Only use Day & Night Nurse for the shortest period of time necessary

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. 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, Day & Night Nurse Capsules can have side effects, but not everybody gets them: Older people are more prone to these side effects.

The following side effects may occur:

Drowsiness, dizziness, blurred vision, nervousness, anxiety, tremor, hallucinations (particularly in children) have been reported rarely, difficulty concentrating, unsteadiness, clumsiness, headache, dry mouth, nausea, vomiting, diarrhoea, constipation, ringing in the ears, irritability, sleep disturbance, loss of appetite, difficulty passing urine, skin rashes, rapid heart rate and shaking.

120 mm

20 mm

30 mm

30 mm

PHARMA CODE REF. IS: XXXX

400 mm

200 mm

30 mm

30 mm

20 mm

PHARMA CODE REF. IS: XXXX

# REVERSO (BACK)

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

- **Allergic reactions** which may be severe such as skin rash, itching sometimes with swelling of the mouth or face or shortness of breath. Very rare cases of serious skin reactions have been reported
- **Skin rash or peeling or mouth ulcers**
- **Breathing problems.** These are more likely if you have experienced them before when taking other painkillers (such as ibuprofen and aspirin)
- **Unexplained bruising and bleeding**
- **Confusion, feeling restless, sweating, shaking, shivering, sudden jerks of muscles or increased blood pressure (these may be symptoms of serotonin syndrome)**
- **Difficulty passing urine**
- **Inflammation of the colon** due to insufficient blood supply (ischaemic colitis)
- **Stomach ache, sudden weight loss, loss of appetite and yellowing of the eyes and skin**
- **Restlessness, nervousness, feeling irritable, increased energy and sleep disturbances,** which are more likely to affect children
- **Sudden severe headache**
- **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 & Night Nurse. See section 2
- **Generalized rash, red and scaly with bumps** under the skin and **vesicles** associated with **fever** at the beginning of treatment (generalized acute exanthematous pustulosis)
- **Reduced blood flow to the optic nerve** (Ischaemic optic neuropathy).

These effects are rare.

**Night-time Capsules only:**

- **dependence and addiction** (see section "How do I know if I am addicted?") - unknown frequency

**Drug Withdrawal**

When you stop taking Night Nurse, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

**How do I know if I am addicted?**

If you notice any of the following signs whilst taking Night Nurse, it could be a sign that you have become addicted.

- You need to take the medicine for **longer** than advised.
- You feel you need to use **more** than the recommended dose.

- You are using the medicine for reasons **other than** those indicated.
- When you stop taking the medicine you **feel unwell**, and you **feel better** once taking the medicine again. If you notice any of these signs, it is important you talk to your doctor or pharmacist.

**If you do get any side effects**, even those not mentioned in this leaflet, tell your doctor or pharmacist.

You can also report side effects directly via the Yellow card scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App store. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Day & Night Nurse Capsules

**Keep out of the sight and reach of children.** Do not use this medicine after the 'EXP' date shown on the pack. Do not store above 25°C.

## 6. Further information

**Day-time Capsules**

**Active ingredients** Paracetamol 500 mg, Pseudoephedrine Hydrochloride 30 mg and Pholcodine 5 mg.

**Other ingredients** Sodium starch glycolate, magnesium stearate (E 572), sodium lauryl sulphate, gelatin and colours quinoline yellow (E 104), allura red (E 129), titanium dioxide (E 171) and printing ink (containing shellac, iron oxide black (E 172), propylene glycol (E 1520) and ammonium hydroxide (E 527).

**Allura red is an azo dye and may cause allergic reactions.**

**Night-time Capsules**

**Active ingredients** Paracetamol 500 mg, Promethazine Hydrochloride 10 mg and Dextromethorphan Hydrobromide 7.5 mg.

**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) and ammonium hydroxide (E 527).

This product contains 24 capsules (18 yellow/ orange daytime capsules and 6 green/white night-time capsules).

**The marketing authorisation holder** is GlaxoSmithKline Consumer Healthcare (UK) Trading Limited, Brentford, TW8 9GS, U.K.

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

This leaflet was last revised in July 2020.

Trade marks are owned by or licensed to the GSK group of companies.

400 mm