

WINAMOL NIGHT PAIN TABLETS

Paracetamol/ Diphenhydramine Hydrochloride (500mg/25mg)

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What WINAMOL NIGHT PAIN is used for

It is used for the short term treatment of bedtime pain, for example rheumatic and muscle pain, backache, toothache, migraine, headache and period pain which is causing difficulty in getting to sleep.

How WINAMOL NIGHT PAIN works

It contains paracetamol and diphenhydramine hydrochloride. Paracetamol is an analgesic which works to reduce fever and to relieve pain while diphenhydramine hydrochloride is an antihistamine which helps to treat allergic reactions.

Before you use WINAMOL NIGHT PAIN

-When you must not use it

Tell your doctor before using WINAMOL NIGHT PAIN if you

- are allergic to paracetamol, diphenhydramine hydrochloride or other constituents.
- have Porphyria (liver disorders that negatively affecting the skin or nervous system).

-Pregnancy and breastfeeding

Tell your doctor or pharmacist if you are pregnant, planning to get pregnant or are breastfeeding. WINAMOL NIGHT PAIN should only be used during pregnancy if the expected benefit to mother is greater than any possible risk to fetus.

It should not be used whilst breast feeding without medical advice.

-Before you start to use it

- Should not be used with other antihistamine-containing preparations, including those used on the skin.
- The lowest dose necessary to achieve efficacy should be used for the shortest duration of treatment.
- Not recommended for children under 16 years of age except on medical advice.
- Patients should not take the tablets for more than 7 consecutive nights without consulting their doctor.
- Elderly: Should not be taken by elderly patients with confusion. Sedating antihistamines may cause confusion and paradoxical excitation in the elderly.
- Caution should be exercised in those with moderate to severe hepatic or renal impairment.

-Taking other medicines

Inform your doctor or pharmacist before taking this medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and WINAMOL NIGHT PAIN may interfere with each other. They may be affected by this product or may affect how well it works.

You should talk to you doctor or pharmacist if you are on the following:

- Metoclopramide, domperidone or colestyramine.
- Flucloxacillin
- Central nervous system depressants (e.g. codeine, tranquilizers, hypnotics and anxiolytics)
- Other antihistamines.
- Monoamine Oxidase inhibitors (MAOIs)
- anticholinergic drugs (e.g. atropine and tricyclic antidepressants)
- Cytochrome p450 isoenzyme CYP2D6 (e.g. metoprolol and venlafaxine)

How to use WINAMOL NIGHT PAIN

-How much to use

Always use WINAMOL NIGHT PAIN exactly as your doctor has prescribed. You should check with your doctor or pharmacist if in doubt.

The usual dose:

Adults (including the elderly) and children aged 16 years and over:

Two tablets to be taken 20 minutes before bedtime. Maximum daily dose: Two tablets (1000 mg paracetamol, 50 mg diphenhydramine hydrochloride) in 24 hours.

Other products containing paracetamol may be taken for daytime pain relief but at a reduced maximum dose of 6 tablets in 24 hours. The dose should not be repeated more frequently than every four hours.

-When to use it

Use as directed by your doctor or pharmacist.

-How long to use it

Continue taking WINAMOL NIGHT PAIN as your doctor recommended. If symptoms persist, consult your doctor.

-If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

-If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using WINAMOL NIGHT PAIN

-Things you must do

- Inform your doctor or pharmacist if symptoms persist after taking this medication.
- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking WINAMOL NIGHT PAIN

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- Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- Do not take more than the recommended dose unless your pharmacist or doctor tells you.
- Do not take any new medicines without consulting your doctor.
- Do not give WINAMOL NIGHT PAIN to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

May cause drowsiness, dizziness, blurred vision, cognitive and psychomotor impairment, which can seriously affect individual's ability to drive and use machinery. If affected they should not drive or operate machinery.

Side effects

Like all medicines, WINAMOL NIGHT PAIN can cause side effects, although not everybody gets them.

If symptoms persist, do not take the medicine and refer to the doctor.

This preparation contains Paracetamol.

Do not take any other Paracetamol containing medicines at the same time.

Allergy alert: Paracetamol may cause severe skin reactions. Symptoms may include skin reddening, blisters or rash.

Tell your doctor if you notice any of the following common side effects or notice any other effects not listed:

- low number of platelet count and white blood cells in the blood.
- hypersensitivity and allergic reaction.
- wheezing, coughing
- liver dysfunction
- fatigue
- sedation, drowsiness, dizziness
- dry mouth
- excess of unmeasured anions

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and disposal of WINAMOL NIGHT PAIN

-Storage

Store below 30°C. Protect from light.

-Disposal

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.

Product description

-What it looks like

Oblong shape bilayer tablet with white colour on top and mottled blue colour on bottom.

-Ingredients

-Active ingredient

Paracetamol and Diphenhydramine hydrochloride

-Inactive ingredients

Colloidal Anhydrous Silica, Microcrystalline Cellulose, Sodium Benzoate, Pregelatinized Starch, Povidone K25, Stearic Acid and Brilliant Blue (Lake)

-MAL number

Manufactured by and Product

Registration Holder

KCK Pharmaceutical Industries Sdn. Bhd.

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Date of revision

21/05/2025

Serial Number

NPRA (R2) 25/051