

**PATIENT PACKAGE INSERT
IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS
(PREPARATIONS) - 1986**

The medicine is dispensed
without a doctor's prescription

Acamol® Tsinun Classic Night Caplets

Composition

Each caplet contains:
Paracetamol 500 mg
Pseudoephedrine hydrochloride 25 mg
Chlorpheniramine maleate 2 mg

For the list of inactive ingredients in the preparation, see section 6 – “Further Information”.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine is dispensed without need for a doctor's prescription and is intended for adults and children from the age of 6 years and above. Take the medicine properly. Consult a pharmacist if you need further information.

Refer to the doctor if the fever persists for more than 3 days or if the signs of the ailment worsen or do not improve after 5 days despite use of the medicine, or in any case in which new symptoms occur.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for the relief of common cold and nasal congestion, accompanied by fever and pains – for night care.

Therapeutic group:

Paracetamol - analgesic and antipyretic.

Pseudoephedrine hydrochloride - relieves nasal congestion.

Chlorpheniramine maleate - antihistamine.

2. BEFORE USING THE MEDICINE

☒ Do not use this medicine:

- Do not use the medicine when you are pregnant or breastfeeding.
- if you are sensitive (allergic) to paracetamol, pseudoephedrine, chlorpheniramine, to another antihistamine or to other decongestants or to any of the other ingredients of the medicine (see section 6).
- if you have asthma.
- if you are being concomitantly treated with medicines from the monoamine oxidase inhibitors group (for depression) or within 14 days of discontinuing treatment with them.
- if you are receiving other decongestants, beta blockers.
- if you have severe heart disease or severe hypertension, a severe liver disease, impaired kidney function, overactive thyroid gland, diabetes, glaucoma.
- Do not use this preparation concomitantly with other paracetamol-containing preparations (if you are uncertain whether the medicine you are taking contains paracetamol, consult a doctor or pharmacist).

Special warnings regarding use of the medicine

- If you have developed skin side effects in the past as a result of taking paracetamol-containing preparations, do not take preparations containing paracetamol, so that severe skin effects will not recur.
- The preparation contains paracetamol which may cause liver damage when:
 - given at a dosage higher than recommended or for a prolonged period.
 - consuming alcoholic beverages during the course of treatment.
 - taking additional medicines which affect liver function.
- Do not use this medicine frequently without consulting a doctor.
- Do not take additional fever reducers and pain relievers or cold medicines without consulting a doctor or pharmacist, to prevent paracetamol overdose or poisoning.
- Do not take additional medicines from the “Acamol family” and/or other paracetamol-containing preparations.
- Inform the doctor if you are due to undergo laboratory tests, since treatment with the medicine may interfere with the results.
- Avoid taking a high dosage (within the recommended limit) of this medicine when fasting.
- If you are sensitive to any food or medicine, inform the doctor before taking the medicine.
- The preparation contains lactose and may cause allergy in people sensitive to lactose.

Before treatment with Acamol® Tsinun Classic Night, tell the doctor if you are suffering, or have suffered in the past, from:

- Disease or impaired function of the heart and/or blood vessels
- Hypertension
- Problem with the eyes (e.g., glaucoma)
- Liver disease or impaired liver function
- Impaired function of the kidney (e.g., a pheochromocytoma-type tumor) or urinary system (e.g., difficulty passing urine)
- Digestive system problem (e.g., ulcer)
- Thyroid problem
- Prostate problem
- Diabetes
- Alcoholism
- Increased restlessness
- Viral jaundice
- Epilepsy
- Asthma
- Bronchitis

If you are taking, or have recently taken, other medicines, including non-prescription medicines and food supplements and vitamins, tell the doctor or pharmacist.

In particular inform the doctor or pharmacist if you are taking a medicine from the following groups or if you have just finished treatment with the medicine:

- Medicines which stimulate the central nervous system (e.g., appetite suppressants).
- Medicines to treat asthma (from the sympathomimetics group).
- Medicines which suppress the central nervous system (e.g., sedatives, hypnotics, medicines for Parkinson's, for epilepsy, antiallergics [e.g., antihistamines that cause drowsiness], surgical anesthetics and narcotic analgesics).
- Medicines to treat anxiety.
- Anticoagulants, especially warfarin.
- Antidepressants (including MAO inhibitors – see section 2, “Do not use this medicine”, or tricyclic antidepressants).
- Cough and cold medicines (e.g., other medicines for nasal congestion - see section 2, “Do not use this medicine”).
- Methyldopa or other antihypertensives (e.g., beta blockers - see section 2, “Do not use this medicine”, alpha blockers or vasodilators) and heart medicines.
- Anticholinergics or medicines with anticholinergic activity (e.g., abdominal antispasmodics).
- Preparations that stimulate liver enzyme activity (e.g., phenytoin [for convulsions], barbiturates).
- Anticonvulsant medicines (to treat epilepsy).
- Other analgesics and anti-inflammatories (in prolonged use).
- Metoclopramide or domperidone (to treat nausea, vomiting and other digestion problems).
- Chloramphenicol or rifampicin (antibiotics).
- Probenecid (to treat gout).
- Cholestyramine (to reduce excessive blood fats).
- Lopinavir (for viral infection).
- Oral contraceptives.
- Medicines to treat migraines (ergot alkaloids).
- Digoxin.
- Oxytocin.

Use of the medicine and food

The medicine can be taken without regard to food.

Use of this medicine and alcohol consumption

During the course of treatment with this medicine do not consume alcohol due to increased risk of liver damage.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, do not use this medicine.

Driving and use of machinery

Do not drive or operate dangerous machinery while using the medicine, as this medicine may impair alertness. Children should be cautioned against riding bicycles or playing near roads and the like.

Use in children

This medicine is intended for adults and children above the age of 6 years, see section 3.

Parents must inform the attending doctor of any side effects as well as any other medicine being given to the child.

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