

=====

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

Read the package insert carefully in its entirety before using this medicine.

ACAMOL[®] TSINUN NIGHT
Caplets

DRUGS-ABOUT.COM

COMPOSITION

Each caplet contains:

Paracetamol	500 mg
Pseudoephedrine hydrochloride	25 mg
Chlorpheniramine maleate	2 mg

Inactive Ingredients

Microcrystalline cellulose, Opadry 31F32870 yellow (lactose, hydroxypropyl methyl cellulose, titanium dioxide, macrogol 4000 [polyethylene glycol], iron oxide yellow, iron oxide red, iron oxide black), povidone, sodium starch glycolate (from potato), stearic acid, magnesium stearate, silicone dioxide.

THERAPEUTIC ACTIVITY

The medicine is intended for the symptomatic relief of common cold and nasal congestion associated with fever and pain. Night care medicine.

WHEN SHOULD THE PREPARATION NOT BE USED?

Do not use this medicine if you are pregnant or breastfeeding.
Do not use this medicine if you are sensitive to any of its ingredients.
Do not use this medicine if you suffer from asthma.
Do not use this medicine concomitantly with monoamine oxidase inhibitors (for depression) or within 14 days of discontinuing such treatment.

Do not take this medicine without consulting a doctor before starting treatment

if you are suffering, or have suffered in the past, from impaired function of the heart and/or vascular system, the eyes (e.g. glaucoma), the liver, the kidney/urinary tract, the digestive system (e.g. ulcer), the thyroid gland, the prostate gland, diabetes, hypertension, alcoholism, or viral jaundice.

HOW WILL THIS MEDICINE AFFECT YOUR DAILY LIFE?

Use of this medicine may impair alertness, and therefore caution should be exercised when engaging in activities such as driving a car, operating dangerous machinery, and in any other activity which requires alertness.
Children should be cautioned against engaging in activities such as bicycle riding or playing near roads and the like.

Do not drink wine or alcoholic beverages while under treatment with this medicine because paracetamol may cause liver damage.

WARNINGS

Do not use this medicine frequently or longer than 10 consecutive days without consulting your doctor - see below.

If you are sensitive to any type of food or medicine, inform your doctor before commencing treatment with this medicine.

If you have to undergo laboratory tests, consult your doctor as this drug may affect the results.

Avoid exceeding the recommended dosage while fasting.

Do not take additional fever-reducing and pain-relieving medicines, or medicines for common cold without consulting a doctor or a pharmacist, in order to prevent paracetamol overdose/toxicity.

DRUG INTERACTIONS

If you are taking another drug concomitantly or if you have just finished treatment with another medicine, inform the attending doctor, in order to prevent hazards or lack of efficacy arising from drug interactions.

This is especially important for medicines belonging to the following groups: stimulants of the central nervous system (appetite suppressants), drugs affecting the central nervous system (e.g. tranquilizers, hypnotics, drugs for parkinsonism, epilepsy, antiallergic, anesthetics for operations and narcotic analgesics), anticoagulants, antidepressants (including MAOI – see above), antihypertensives and medicines for the heart, cough and cold preparations, anticholinergic drugs or drugs with anticholinergic activity (e.g. drugs for the treatment of abdominal spasms), hepatic enzyme inducing agents e.g. barbiturates or phenytoin (for seizures) or long term treatment with another analgesic and anti-inflammatory medicines.

SIDE EFFECTS

In addition to the desired effect of the medicine, adverse reactions may occur during the course of taking this medicine, for example: dryness of the mouth – it is recommended to use artificial saliva and especially you have to be strict with your mouth hygiene to avoid increase of caries, blurring of vision, drowsiness, dizziness, nervousness or insomnia.

Effects that require special attention

Allergic reactions (rash) (rare): stop treatment and refer to your doctor.

In the event that you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult your doctor immediately.

Adverse Reactions And Drug Interactions In Children

Parents must inform the attending doctor about any side effects, as well as any additional medicine being taken by a child.

See above for details of special side-effects and drug interactions.

RECOMMENDED DOSAGE UNLESS OTHERWISE PRESCRIBED BY THE DOCTOR:

Adults and children over 12 years of age: 1-2 caplets at bedtime.

Patients over 60 years of age should consult their doctor before taking this medicine because they may be sensitive to these kind of medicines.

Children 6-12 years: ½ caplet before bedtime.

Do not exceed the recommended dosage.

This medicine is not usually intended for administration to children under 6 years of age.

If fever continues for more than 3 days, the doctor should be consulted. If fever is absent but your condition has not improved within 7 days the doctor should be consulted.

DIRECTIONS FOR USE

Do not chew! Swallow the caplets with a small amount of water.

Avoid Poisoning!

This medicine, and all other medicines, must be stored in a safe place out of the reach of children and/or infants, in order to avoid poisoning.

If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

Do not induce vomiting unless explicitly instructed to do so by a doctor!

Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.

STORAGE

Store this medicine in a cool and dry place.

Even if kept in their original container and stored as recommended, medicines may be kept for a limited period only. Please note the expiry date of the medicine! In case of doubt, consult the pharmacist who dispensed the medicine to you.

Do not store different medications in the same package.

Drug Registration No.: 120243004400

MANUFACTURER

Teva Pharmaceutical Industries Ltd.

P.O. Box 3190, Petach-Tikva

DRUGS-ABOUT.COM