

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

The medicine is dispensed
without a doctor's prescription

Acamol® Tsinun & Shapa'at Night Caplets

Composition

Each caplet contains:

Paracetamol 500 mg
Pseudoephedrine hydrochloride 30 mg
Dextromethorphan hydrobromide 15 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 of a doctor's prescription and is intended for adults and children from the age of 12 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 cough, cold and nasal congestion, accompanied by fever and pains – for night care.

Therapeutic group:

Paracetamol - analgesic and antipyretic.
Pseudoephedrine - relieves nasal congestion.
Dextromethorphan - cough suppressant.
Chlorpheniramine - 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, dextromethorphan, chlorpheniramine, to another antihistamine or to other decongestants or to any of the other ingredients of the medicine (see section 6).
- if you are being concomitantly treated with medicines from the monoamine oxidase inhibitors (MAOI) group for depression or within 14 days of discontinuing treatment with them.
- if you have asthma.
- if you have severe heart disease or hypertension.
- if you have lung disease.
- if you are suffering from a chronic cough.
- if you are receiving other decongestants, beta blockers.
- 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).
- if you have the following diseases or conditions: blood vessel disease, a severe disease of the liver or kidneys, overactive thyroid gland, high intraocular pressure (glaucoma), prostate problems, breathing difficulties or diabetes.

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.
- Inform the doctor if you are due to undergo laboratory tests, since treatment with the medicine may interfere with the results.
- Do not take additional medicines from the "Acamol family" and/or other paracetamol-containing preparations.
- 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.

Before treatment with Acamol® Tsinun & Shapa'at 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 (e.g., coronary artery disease)
- A disease or impairment of the respiratory system, e.g., asthma, bronchitis, cough accompanied with phlegm, for example, as a result of smoking, persistent cough, slow breathing. If the cough is accompanied with fever, rash or persistent headache.
- Hypertension
- Problems 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
- Impaired thyroid function
- Impaired prostate function
- Diabetes
- Alcoholism
- Increased restlessness
- Epilepsy
- Viral jaundice
- Impairment of the nervous system
- Impaired function of the digestive system (e.g., ulcer)

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 which suppress the central nervous system (e.g., sedatives, hypnotics, medicines for Parkinson's, for epilepsy, antiallergics, 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").
- Medicines to treat asthma (from the sympathomimetics group).
- Methyldopa or other antihypertensives (e.g., beta blockers, see section 2, "Do not use this medicine", alpha blockers or vasodilators) and heart medicines (e.g., amiodarone, quinidine).
- 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

Take the medicine after a meal.

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 children above the age of 12 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.

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain.

The usual dosage is generally:

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

Patients above the age of 60 years: consult the doctor before using this medicine, as they may be sensitive to preparations of this kind.

Upon concomitant use of Acamol® Tsinun & Shapa'at Day, exchange a dose of Acamol® Tsinun & Shapa'at Day with a dose of Acamol® Tsinun & Shapa'at Night and do not take it as a supplement to the maximum dosage recommended above for Acamol® Tsinun & Shapa'at Night.

Do not exceed the recommended dose.

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.

Directions for use

Do not chew! The caplet can be halved on the score line.
Swallow the caplet with a small amount of water.

If you took an overdose or if a child accidentally swallowed the medicine, immediately refer to a doctor or to a hospital emergency room and bring the package of the medicine with you. Do not induce vomiting without explicit instruction from the doctor!

Even if you feel well, immediate treatment is essential, **due to the risk of developing severe liver damage.** Side effects can be nausea and vomiting, diarrhea, loss of appetite, abdominal pains, flatulence, increased sweating, pain or tenderness in the upper abdomen and they may not reflect the severity of the liver damage.

Additional signs of overdose: blurred vision, confusion, difficulty passing urine, slow breathing and extreme nervousness, severe pancreatitis may also occur.

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

If you have further questions regarding use of the medicine, consult a doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of this medicine may cause side effects. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Severe side effects

Stop treatment and refer to the doctor immediately:

- If severe allergic reactions occur, such as rash and itching, swelling of the face, lips, tongue, throat and/or limbs, which may cause breathing or swallowing difficulties.
- Paracetamol may, in rare cases, cause the appearance of severe skin diseases, whose signs can be: redness, rash, blisters, widespread skin damage. Severe skin side effects may occur even if you have taken preparations containing the active ingredient paracetamol in the past without any problem. If skin side effects occur, stop treatment and refer to the doctor immediately.
- Hallucinations (rare).
- Problem passing urine, especially in men with a prostate problem.
- If signs of changes in the blood system occur, such as: unexplained tiredness, bleeding, anemia, bruises, development of inflammations more easily.
- Irregular heart rhythm, shortness of breath, tightness of the chest.
- Liver problems, including jaundice (yellowing of the skin and eyes).
- Severe pancreatitis (as a result of overdose).
- Lack of coordination.
- Confusion among the elderly.
- Restlessness, sleep disturbances.

Additional side effects:

- Dizziness, sleepiness, tiredness
- Dry mouth, nose and throat (it is recommended to use saliva substitutes and to maintain dental hygiene, in view of the fact that caries may be more common)
- Lack of appetite, heartburn
- Tension, nervousness, lack of sleep, nightmares, depression
- Decreased blood pressure, palpitations
- Rash, sensitivity to light
- Nausea, vomiting, diarrhea, abdominal pain, digestive system disturbances, increased viscosity of sputum (may cause cough or phlegm)
- Headache, ringing in the ears, blurred vision, inability to concentrate
- Tremor
- Malaise, muscle weakness, muscle contractions
- Hyperactivity in children

If a side effect occurs, if any of the side effects worsen, or if you are suffering from a side effect not mentioned in the leaflet, consult the doctor.

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.
- Do not use the medicine after the expiry date (Exp. Date) that appears on the package. The expiry date refers to the last day of that month.
- **Store in a dry place, below 25°C.**
- Do not discard medicines in the waste water or waste bin. Ask the pharmacist how to dispose of medicines that are not in use. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredients, the medicine also contains:

Microcrystalline cellulose, sodium starch glycolate, hypromellose, silicon dioxide, stearic acid, magnesium stearate, polyvinyl alcohol, macrogol 3350 (polyethylene glycol), talc, titanium dioxide, erythrosine aluminum lake, FD&C blue #1/brilliant blue FCF aluminum lake.

Each caplet contains 0.588-0.882 mg sodium.

What the medicine looks like and the contents of the package:

Purple, capsule-shaped, biconvex, film-coated tablet, plain on one side and scored on the other side of the tablet. The package contains 14 caplets.

Manufacturer and license holder:

Teva Pharmaceutical Industries Ltd., P.O.B. 3190, Petah-Tikva.

This leaflet was checked and approved by the Ministry of Health in December 2014.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

136.48.31129



322K001850215