# 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

the list of inactive ingredients in the paration, see section 6 - "Further preparation, see section 6 - 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.

# 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

Therapeutic group:
Paracetamol - analgesic and antipyretic.
Pseudoephedrine hydrochloride - relieves Chlorpheniramine maleate - antihistamine.

BEFORE USING THE MEDICINE

- ZDo 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 have asthma.
- if you have severe heart disease or 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 th 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.

- 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 pair relievers or cold medicines.

  - Do not take additional tever 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.
- 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 anv food  $\Omega$
- medicine, inform the doctor before taking the medicine. The preparation contains lactose and 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 ne past, from: Disease or impaired function of the heart and/or blood vessels

# disease or impaired Impaired function of the kidney (e.g., a phaeochromocytoma-type tumor) or urinary system (e.g., difficulty passing

Problem with the eyes (e.g., glaucoma)

Digestive system problem (e.g., ulcer)

Increased restlessness

- Thyroid problem Prostate problem Diabetes
- Viral jaundice Epilepsy **Asthma**
- If you are taking, or have recently taken, other medicines, including non-prescription medicines and food

Alcoholism

Hypertension

- 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:
- 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 artidopressants)
- 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). anti-
- Other analgesics and a inflammatories (in prolonged use).
- (to treat nausea, vomiting and other digestion problems).

  Chloramphenical
- (antibiotics).

  Probenecid (to treat gout).

  Cholestyramine (to reduce excessive blood fats).

- Lopinavir (for viral infection). Oral contraceptives

### ■ 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.

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

■ Pregnancy and breastfeeding

### ■ 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. H 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. HOW SHOULD YOU USE THE MEDICINE?

# Check with the doctor or pharmacist if you are uncertain.

The usual dosage, unless instructed otherwise by the doctor:
Adults and children above 12 years of age: 1-2 caplets at bedtime.

Children ages 10-12 years: 1 caplet at bedtime.

Children ages 6-9 years:  $\frac{1}{2}$  caplet 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 Classic Day, exchange a dose of Acamol® Tsinun Classic Day with a dose of Acamol® Tsinun Classic Night, and do not take it as a supplement to the recommended dosage of Acamol® Tsinun Classic Night. Do not exceed the recommended

Refer to the doctor if the fever persists ferer 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 or crush! The caplet can be halved on the score line. Swallow the caplet with a small amount

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,

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

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 (rare)

- swallowing difficulties (rare)
  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)
- Hallucinations (rare)
  Difficulty passing urine in men, especially when there is a prostate problem Tightness in the chest Change in heart rate Liver problems, including jaundic (yellowing of the skin and eyes) Liver
- If signs of changes in the blood system occur, such as: anemia, bleeding, bruises, development of inflammations more easily, unexplained tiredness Severe pancreatitis (as a result of overdose)
- Lack of coordination Confusion among the elderly Additional side effects: Dizziness, sleepiness, tiredness Lack of appetite, heartburn, nausea, vomiting, diarrhea, abdominal pain, digestion problem
  - ongestion problem

    Dry mouth it is recommended to use saliva substitutes; in particular, be sure to maintain dental hygiene, in view of the fact that caries may be more
  - common
- Low blood pressure, palpitations Increased bronchial secretion (which may cause cough or phlegm)
- Muscle weakness, transient muscle contraction Ringing in the ears General unwell feeling Difficulty passing urine Blurred vision, sensitivity to light

ack of concentration, headache,

- depression nervousness or lack of Nightmares, sleep, tension
- Hyperactivity in some 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.

- 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, povidone, sodium starch glycolate (from potato), lactose monohydrate, hypromellose, stearic acid, titanium dioxide, magnesium stearate, silicon dioxide, polyethylene glycol, iron oxide yellow, iron oxide red, iron oxide black.

Each caplet contains: 0.25-0.38 mg sodium

6.48 mg lactose. What the medicine looks like and the contents of the package:

Yellow, capsule-shaped, film-coated biconvex tablet. One side has a score line and the other side is plain. The package contains 14 caplets.

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

Manufacturer and license holder: Teva Pharmaceutical Industries Ltd., P.O.B. 3190, Petah-Tikva.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 120.24.30044

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Medicines to treat migraines (ergot alkaloids). Digoxin. Oxytocin.