

**PATIENT LEAFLET IN ACCORDANCE  
WITH THE PHARMACISTS'  
REGULATIONS  
(PREPARATIONS) – 1986**  
This 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 information regarding inactive  
ingredients and allergens, see section 2 –  
“Important information about some of the  
ingredients of the medicine” and section 6 –  
“Additional information”.

**Read the entire leaflet carefully before  
using the medicine.** This leaflet contains  
concise information about the medicine. If  
you have additional questions, refer to the  
doctor or the pharmacist.

**Take the preparation according to the  
instructions in the dosage section of this  
leaflet. Consult the pharmacist if you need  
any further information.**

**You should refer to the doctor if the fever  
persists for more than 3 days or if the  
symptoms of the ailment worsen or do  
not improve after 5 days.**

**This medicine is intended for adults and  
children 12 years of age and above.**

**1. WHAT IS THE MEDICINE INTENDED  
FOR?**

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

**Therapeutic class:**

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 this medicine when you are pregnant or breastfeeding.
- If you are sensitive (allergic) to paracetamol, pseudoephedrine, dextromethorphan, chlorpheniramine, other antihistamines or 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 group (MAOI) (for depression) or with reversible inhibitors of monoamine oxidase (RIMAs) or within 14 days of discontinuing treatment with them.
- If you are taking selective serotonin reuptake inhibitors [SSRIs] (against depression or anxiety) or if you have taken them in the last two weeks.
- If you are taking or have taken in the last two weeks antidepressants, antipsychotics, medicines for emotional conditions or medicines for Parkinson's disease.
- If you are being concomitantly treated with other decongestants, other medicines for cough and cold.
- If you are taking medicines for the treatment of heart problems from the beta blockers group.
- If you suffer from very high blood pressure (severe hypertension) or hypertension that is not controlled by medicines, from heart or blood vessel disease or have a history of stroke.
- If you have diabetes.
- If you are a child under 12 years of age.
- Concomitantly with other preparations containing paracetamol (if you are uncertain whether the medicine you are taking contains paracetamol, consult a doctor or pharmacist).
- If you suffer from an overactive thyroid gland.
- If you suffer from high intraocular pressure (glaucoma).
- If you have an acute (sudden) or chronic (long-term) kidney disease or kidney failure.
- If you suffer from pheochromocytoma (a rare tumor of the adrenal gland that affects blood pressure and heart rate).
- If you are taking medicines that increase or suppress appetite or asthma medicines (sympathomimetic medicines).

**Special warnings regarding the use of  
the medicine**

- Cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) have been reported with the use of medicines containing pseudoephedrine. PRES and RCVS are rare conditions that may involve reduced blood supply to the brain. Stop using Acamol Tsinun & Shapa'at Night immediately and seek immediate medical assistance if you develop symptoms that may be signs of PRES or RCVS (see section 4 “Possible side effects” for the symptoms).
- If you developed skin side effects in the past as a result of taking preparations containing paracetamol, do not take preparations containing paracetamol, so that severe skin side effects will not recur.
- The preparation contains paracetamol, which may cause liver damage when:
  - Given at a higher dosage than recommended or for a prolonged period.
  - Alcoholic beverages are consumed during the course of treatment.
  - Additional medicines which affect liver function are taken.
- Do not use this medicine frequently without consulting the doctor.
- Do not take additional antipyretics and analgesics or cold medicines without consulting a doctor or a pharmacist, to prevent paracetamol overdose or poisoning.
- Inform the doctor if you are about to have laboratory tests, as the treatment with the medicine may affect the results.
- Do not take additional medicines from the “Acamol family” and/or other preparations containing paracetamol.
- Avoid taking a high dosage (within the recommended limit) of this medicine when fasting.
- If you are sensitive to any type of food or medicine, inform your doctor before starting treatment with this medicine.
- Taking this medicine regularly for a long period may cause addiction. Take this medicine as specified in this leaflet.

**Before the treatment with Acamol Tsinun  
& Shapa'at Night, tell the doctor if you  
suffer or have suffered in the past from:**

- A disease or impaired function of the heart and/or blood vessels (such as: coronary artery disease – blockage of arteries or veins)
- A disease or impairment of the respiratory system, such as: asthma, bronchitis, persistent cough, cough accompanied by fever, rash or continuous headache or any other lung problem
- Liver disease or impaired liver function
- Impaired kidney function
- Problems passing urine or enlarged prostate (causes frequent urination)
- Impaired function of the thyroid gland
- Impaired function of the prostate gland
- You are addicted or have been addicted to opioids, alcohol, prescription medicines or illegal drugs
- You have recently suffered from symptoms of alcohol or drug withdrawal, such as: emotional turmoil, anxiety, sweating or tremors
- Epilepsy
- Jaundice

**Drug interactions**

**If you are taking, or have recently taken,  
other medicines including non-prescription  
medicines, nutritional supplements and  
vitamins, tell your 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 these medicines:

- Anti-cholinergic medicines (for the treatment of spasms and cramps, such as atropine)
- Selective serotonin reuptake inhibitors [SSRIs] (against depression or anxiety) or if you have taken them in the last two weeks (**see section 2, “Do not use this medicine”**)
- Anticoagulants, especially warfarin
- Antidepressants (**including MAO inhibitors, RIMAs – see section 2, “Do not use this medicine”**) or if you have taken them in the last two weeks
- Tricyclic antidepressants
- Medicines for depression, for psychiatric diseases, for Parkinson or if you have taken them in the last two weeks (**see section 2, “Do not use this medicine”**)
- Moclobemide – antidepressant
- Other antihistamines including cough and cold medicines (such as: other nasal decongestants, **see section 2, “Do not use this medicine”**) that make you feel drowsy
- Medicines for lowering blood pressure, such as: guanethidine, methyl dopa, adrenergic neuron blocker, debrisoquine, bethyrium and bethanidine or other medicines for lowering blood pressure (such as: beta blockers – **see section 2, “Do not use this medicine”**)
- Preparations that stimulate liver enzyme activity (such as: barbiturates)
- Anticonvulsant medicines (for the treatment of epilepsy), such as: phenytoin, carbamazepine
- Metoclopramide or domperidone (for treatment of nausea, vomiting and other digestive problems)
- Chloramphenicol or rifampicin (antibiotics)
- Probenecid (for treatment of gout)
- Cholestyramine (for reduction of excess blood lipids)
- Non-steroidal anti-inflammatory drugs
- Medicines for anxiety and sleep
- Contraceptive pills
- Medicines for the treatment of migraines (ergot alkaloids)
- Cardiac glycoside (a medicine given for the treatment of heart rhythm disorders or heart failure, such as digoxin)
- Medicines for heart problems, such as: quinidine and amiodarone
- Oxytocin (a medicine given during labor for uterus contraction)
- Terbinafine for the treatment of fungal infections
- Cinacalcet for the treatment of secondary parathyroid gland overactivity
- Methadone for the treatment of severe pain
- Inform the doctor or pharmacist if you are taking flucloxacillin (an antibiotic) because of a severe risk of blood and fluid abnormality (high anion gap metabolic acidosis) which requires urgent treatment and may happen especially in cases of severe kidney impairment, sepsis (a condition in which bacteria and their toxins are in the blood, leading to organ damage), malnutrition, chronic alcoholism, and in cases in which the maximum daily dosage of paracetamol is used

If you are taking antidepressants or antipsychotics together with Acamol Tsinun & Shapa'at, you may experience mental changes (such as: agitation, hallucinations, coma), and other symptoms such as: fever above 38 degrees Celsius, increased heart rate, unstable blood pressure, exaggerated reflexes, muscle stiffness, lack of coordination and/or symptoms related to the stomach and intestine (nausea, vomiting, diarrhea).

**Use of the medicine and food**

The medicine should be taken after a meal.

**Use of this medicine and alcohol  
consumption**

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

**Pregnancy and breastfeeding**

Do not use this medicine if you are pregnant or breastfeeding.

**Driving and operating machinery**

Do not drive or operate dangerous machinery while using the medicine, as this medicine may affect alertness, you may feel drowsy, dizzy or have blurry vision. Children should be cautioned against riding a bicycle or playing near a road etc.

**Use in children**

This medicine is intended for children above 12 years of age, see section 3. Parents must report to the treating doctor all side effects and any additional medicine given to the child.

**Additional information**

The active ingredient pseudoephedrine has a potential for abuse. An increased dosage may be toxic. Prolonged use may lead to taking a dose higher than recommended in order to achieve the desired effect, resulting in increased risk of an overdose. Do not exceed the recommended dosage and duration of treatment (see section 3).

**Important information about some of the  
ingredients of the medicine**

Each caplet contains 0.588-0.882 mg sodium. This medicine contains less than 23 mg of sodium per caplet, and is therefore considered sodium-free.

**3. HOW SHOULD YOU USE THE  
MEDICINE?**

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

**The generally accepted dosage is:**

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

Upon concomitant use of Acamol Tsinun & Shapa'at Day do not exceed a daily dosage of 8 caplets in total. (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).

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

**Do not exceed the recommended dose.**

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

**Method of use**

Do not chew! The caplet can be halved at the score line.

Swallow the caplet with a glass of water.

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

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 pain, bloating, increased sweating, pain or tenderness in the upper abdomen. They may not reflect the severity of liver damage. Muscle cramps, agitation, confusion, sleepiness, impaired level of alertness (consciousness), quick and involuntary eye movements, heart problems (rapid heart rhythm), coordination problems, severe mental disorder accompanied by hallucinations, tendency to become overexcited.

**If you forget to take the medicine** take the following dose as needed, as long as the last dose was taken at least 4 hours before taking the current dose. Do not take a double dose.

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

**If you have any other questions regarding  
the use of the medicine, consult the doctor  
or the 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 experience any of them.**

**Severe side effects**

**Stop the treatment immediately and  
seek urgent medical treatment:**

If you develop symptoms that may be signs  
of posterior reversible encephalopathy  
syndrome (PRES) and reversible cerebral  
vasoconstriction syndrome (RCVS). Signs  
include:

- Sudden appearance of severe headache
- Nausea
- Vomiting
- Confusion
- Convulsions
- Changes in vision

**Stop the treatment and contact the  
doctor immediately:**

- If severe allergic reactions appear, such as: rash and itching, swelling of the face, lips, tongue, throat and/or extremities that can cause difficulty breathing or swallowing
- Paracetamol may, in rare cases, cause the appearance of severe skin diseases whose symptoms can be: redness, rash, blisters, widespread skin damage. Severe skin side effects may appear even if you had no problems in the past taking preparations containing the active ingredient paracetamol. If skin side effects appear, discontinue treatment and refer to a doctor immediately
- Abdominal discomfort
- Dizziness, drowsiness, confusion
- Hallucinations (rare) (hearing sounds and seeing visions that do not exist, thoughts and feelings that are not logical)
- 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, bruising, developing inflammations more easily
- Irregular heart rate, chest pressure
- Sudden and severe abdominal pain or rectal bleeding (in the anus) due to inflammation of the colon as a result of insufficient blood supply
- A decrease of blood flow to the heart that may cause angina pectoris (discomfort or pain in the chest, neck, back, jaw, shoulders, arms) or a heart attack
- A stroke (weakness in the face, arms or legs or speaking problems)
- A sudden onset of fever, skin redness, or many small pustules (possible symptoms of acute generalized exanthematous pustulosis – AGEP), which may occur during the first two days of treatment with this preparation
- Sudden loss of vision
- Liver problems including jaundice (yellowing of the skin and eyes)
- Lack of coordination
- Confusion in the elderly

**Additional side effects:**

**Very common side effects – may affect  
more than 1 in 10 users**

- Headache

**Common side effects – may affect up to  
1 in 10 users**

- Sleeping difficulties, nervousness, dizziness
- Dry mouth or nausea

**Side effects with unknown frequency  
(effects whose frequency has not yet  
been determined)**

- Serious conditions that affect blood vessels in the brain known as posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS)
- Anxiety, feeling of restlessness, irritability, stress or an extreme feeling of happiness
- Sleep disturbances
- Fast or irregular heartbeat or palpitations
- Drowsiness
- High blood pressure
- Abdominal pain, diarrhea, vomiting
- Pain during urination
- Tingling in the hands and feet
- Tremor
- A decrease in blood flow to the optic nerve (ischemic optic neuropathy)
- Dependence and addiction – when you stop taking the medicine you may experience symptoms of withdrawal, including: feeling of restlessness, sleeping difficulties, irritability, anxiety, palpitations, rise in blood pressure, vomiting and nausea, diarrhea, tremor, sweating
- Tiredness
- Dry mouth, loss of appetite, heartburn
- Nightmares, depression, drop in blood pressure, rash, sensitivity to light, nausea, increase in mucus viscosity (may cause cough or phlegm)
- Ringing in the ears, blurred vision, inability to concentrate, malaise, muscle weakness, muscle cramps, hyperactivity in children, problems in blood indicators such as anemia
- Low blood count, hepatitis (severe abdominal pain, nausea, vomiting and loss of appetite)

**If a side effect occurs, if one of the side  
effects worsens, or if you suffer from a  
side effect not mentioned in this leaflet,  
consult your doctor.**

**Reporting side effects**

Side effects may be reported to the Ministry  
of Health by clicking on the link “Report side  
effects due to medicinal treatment” found on  
the Ministry of Health website homepage  
([www.health.gov.il](http://www.health.gov.il)), which will direct you to the online form for reporting side effects, or by clicking on the following link:  
<https://sideeffects.health.gov.il>

**5. HOW TO STORE THE MEDICINE?**

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (Exp. Date) appearing 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 via wastewater or the trash. Ask your pharmacist how to dispose of medicines no longer in use. These measures will help to protect the environment.

**6. ADDITIONAL 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.

**What does the medicine look like and  
what are the contents of the package?**

Purple, biconvex, capsule-shaped film-coated caplet, scored on one side and plain on the other.

The package contains 14 caplets.

**Name and address of the manufacturer  
and license holder:**

Teva Israel Ltd., 124 Dvora HaNevi'a St.,  
Tel Aviv 6944020.

**This leaflet was revised in July 2024.**

**Registration number of the medicine in  
the national drug registry of the Ministry  
of Health:**  
136.48.31129