PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

This medicine is dispensed without a doctor's prescription

Acamol® Tsinun & Shapa'at Day

Caplets

Composition

Each caplet contains:
Paracetamol 500 mg
Pseudoephedrine hydrochloride 30 mg
Dextromethorphan hydrobromide 15 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 day care.

Therapeutic class:
Paracetamol – analgesic and antipyretic.
Pseudoephedrine – relieves nasal congestion.
Dextromethorphan – cough suppressant.

2. BEFORE USING THE MEDICINE

Do not use this medicine:

- If you are sensitive (allergic) to paracetamol, or to pseudoephedrine, or to dextromethorphan, or to other decongestants, or to any of the other ingredients the medicine contains (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 suffer from 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 Day 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.
- 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 Day, 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, persistent cough, cough accompanied by fever, rash or continuous headache
- 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
- 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
- Medicines for lowering blood pressure, such as: guanethidine, methyldopa, adrenergic neuron blocker, debrisoquine, bretylium and bethanidine or other medicines for lowering blood pressure (such as: beta blockers – **see section 2, "Do not use this medicine",** alpha blockers or vasodilators) and medicines for the heart (such as: amiodarone, quinidine)
- Preparations that stimulate liver enzyme activity (such as: phenytoin [for convulsions], 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 (antibiotic)
- Probenecid (for treatment of gout)
- Cholestyramine (for reduction of excess blood lipids)
- Non-steroidal anti-inflammatory drugs
- Contraceptive pills
- Cardiac glycoside (a medicine given for the treatment of heart rhythm disorders or heart failure, such as digoxin)
- Ergot alkaloids – for the treatment of migraine, such as: ergotamine or methysergide
- 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 can be taken regardless of food.

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
If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult a doctor before using the medicine.

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.

Driving and operating machinery
The medicine may make you feel tired and dizzy; therefore, the medicine may affect your ability to drive or use tools or machinery.
Do not drive and operate machinery until you know how the medicine affects you.

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.
Each caplet contains 6.5 mg lactose monohydrate. If your doctor has told you that you have an intolerance to certain types of sugar, consult the doctor before taking this preparation.
The medicine contains FD&C YELLOW #6/SUNSET YELLOW FCF which may cause allergic reactions.

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, every 4-6 hours, up to 4 times a day.
Do not exceed a dosage of 8 caplets a day.
Upon concomitant use of Acamol Tsinun & Shapa'at Night do not exceed a daily dosage of 8 caplets in total. (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 Day).
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 or crush! 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 and 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, bruising, developing inflammations more easily
- Irregular heart rate
- 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

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

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), 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 (hydroxypropyl methylcellulose), silicon dioxide, stearic acid, magnesium stearate, lactose monohydrate, HPMC 2910/hypromellose 15cp, titanium dioxide, macrogol 4000 [polyethylene glycol], D&C yellow #10 aluminum lake, FD&C yellow #6/sunset yellow FCF 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?
Green, biconvex, capsule-shaped film-coated caplet, scored on one side and plain on the other.
The package contains 21 caplets or 35 caplets. Not all package sizes may be marketed.

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:
136.49.31130

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