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

This medicine is dispensed without a doctor's prescription

Acamol® Tsinun Liquigel Day
Liquigel capsules

Composition

Each liquigel capsule contains:

Paracetamol 250 mg

Pseudoephedrine hydrochloride 30 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 and nasal congestion symptoms accompanied by fever and pain – for day care.

Therapeutic class:

Paracetamol – analgesic and antipyretic.

Pseudoephedrine hydrochloride – relieves nasal congestion.

2. BEFORE USING THE MEDICINE

Do not use this medicine:

- If there is a known sensitivity to paracetamol, to pseudoephedrine hydrochloride or to any of the other ingredients of the medicine (see section 6).
- 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 suffer from pheochromocytoma (a rare tumor of the adrenal gland that affects blood pressure and heart rate).
- 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 are being concomitantly treated with additional cold and cough medicines or with other preparations containing paracetamol.
- If you are being treated with medicines from the beta blockers group for the treatment of hypertension.
- If you are being concomitantly treated with medicines for the treatment of depression from the monoamine oxidase inhibitors group (MAOI) or with reversible inhibitors of monoamine oxidase (RIMAs) or within 14 days of discontinuing treatment with them.
- If you are taking medicines that increase or suppress appetite or medicines for the treatment of congestion and asthma (sympathomimetic medicines).
- If you are a child under 12 years of age.

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 Liquigel 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.

Before the treatment with Acamol Tsinun Liquigel Day, tell the doctor if you suffer or have suffered in the past from:

- Kidney or liver function problem
- Alcoholism
- Blockage of arteries or veins
- Impaired function of the thyroid gland
- Problems passing urine or enlarged prostate (which causes frequent urination)
- Jaundice

Drug interactions

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. In particular, inform the doctor or pharmacist if you are taking a medicine from the following groups:

- Anti-cholinergic medicines (for the treatment of spasms and cramps, such as atropine).
- Medicines for lowering blood pressure, such as: guanethidine, methyldopa, adrenergic neuron blocker, debrisoquine, bretylium and bethanidine.
- 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.
- Moclobemide – antidepressant.
- 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).
- Cholestyramine (for the reduction of blood lipid levels).
- Metoclopramide or domperidone (for treatment of nausea, vomiting and other digestive problems).
- Medicines for prevention of blood clots, such as warfarin.
- Contraceptive pills.
- Anticonvulsant medicines (for the treatment of epilepsy, such as: phenytoin, carbamazepine).
- Preparations that stimulate the production of enzymes in the liver (such as: rifampicin, barbiturates).
- Non-steroidal anti-inflammatory drugs.
- Chloramphenicol (antibiotic).
- Probenecid (for treatment of gout).
- 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.

Use of the medicine and food

The medicine can be taken regardless of food. Take the medicine with a glass of water.

Use of the 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.

Breastfeeding:

Small amounts of paracetamol pass into breastmilk. Consult the doctor before use.

Use in children

This medicine is intended for adults and 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

This medicine contains 50 mg of propylene glycol in each capsule.

This medicine contains sorbitol.

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.

Standard dosage when no other instruction from the doctor is given:

Adults and children 12 years of age and above:

2 liquigel capsules every 4-6 hours, up to 4 times a day.

Do not take more than 8 capsules in a 24-hour period.

Upon concomitant use of Acamol Tsinun Liquigel Day with Acamol Tsinun Liquigel Night, do not exceed a total dosage of 8 capsules per 24 hours. Exchange a dose of Acamol Tsinun Liquigel Day with a dose of Acamol Tsinun Liquigel Night, and do not take it as a supplement to the maximum dosage recommended above for Acamol Tsinun Liquigel Day.

Patients above 60 years of age should 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.

Method of use

Do not chew!

The capsule should be swallowed 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. Do not induce vomiting without an 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 pain, swelling, increased sweating, pain or tenderness in the upper abdomen, and they may not reflect the severity of liver damage.

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 a medicine. Wear glasses if you need them.

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

4. SIDE EFFECTS

As with any medicine, using Acamol Tsinun Liquigel Day 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

If you experience any of the following side effects, stop the treatment and refer to the doctor immediately:

- Severe allergic reactions, including: skin rash such as hives (may be accompanied by blisters and flaking of the skin), swelling of the face, lips, tongue, throat that can cause breathing or swallowing difficulties.
- 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.
- Irregular heart rate.
- Hallucinations (hearing sounds and seeing visions that do not exist, thoughts and feelings that are not logical).
- Sudden and severe abdominal pain or rectal bleeding (in the anus) due to inflammation of the colon as a result of insufficient blood supply.
- Sudden loss of vision.
- If signs of changes in the blood system occur, such as: unexplained tiredness, bleeding, bruises, developing inflammations more easily.
- 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 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.

If you experience any of the following side effects, stop the treatment and refer to the doctor:

- Difficulty passing urine (especially in men with prostate problems)

Additional side effects

Very common side effects - may affect more than 1 user out of 10

- Headache

Common side effects - may affect up to 1 user out of 10

- 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 which may cause vision loss

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.

6. ADDITIONAL INFORMATION

In addition to the active ingredients the medicine also contains:

Polyethylene glycol, gelatin, glycerol, purified water, propylene glycol, povidone, dry substance of anidrisorb, quinoline yellow.

The capsules are printed, the dry printing ink contains:

Titanium Dioxide, Shellac, Industrial Methylated Spirit 74 OP, N-Butyl Alcohol, Ethyl Acetate

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

Oblong, transparent, yellow capsules. The word "TEVA" appears on one side and the word "DAY" on the other side.

Each package contains 30 capsules.

Manufacturer and license holder:

Teva Israel Ltd.

124 Dvora HaNevi'a St., Tel Aviv 6944020

This leaflet was revised in August 2024.

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

125.99.30511

teva