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

The 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 the list of inactive ingredients in the preparation, see section 6 – "Further Information".

Read this leaflet carefully in its entirety before using this 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 a doctor's prescription and is intended for adults and children 12 years of age 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 there was no pain relief within 5 days despite use of the medicine.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for the relief of cold symptoms and nasal congestion, accompanied by fever and pains – for daytime care.

Therapeutic group:

Paracetamol - analgesic and antipyretic.
Pseudoephedrine hydrochloride – relieves nasal congestion.

2. BEFORE USING THE MEDICINE

Do not use this medicine:

- Do not use the medicine when you are breastfeeding.
- If there is a known sensitivity to paracetamol or to pseudoephedrine hydrochloride 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 within 14 days of discontinuing treatment with them.
- If you are suffering from a severe heart disease or from very high blood pressure.

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 overdose or paracetamol poisoning.
- 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.

Consult the doctor before commencing treatment if you are suffering, or have suffered in the past, from:

- Disease or impaired function of the heart and/or blood vessels
- Hypertension
- Eye problems (e.g., glaucoma)
- Liver disease or impaired liver function
- Impaired function of the kidney (e.g., a phaeochromocytoma-type tumor) or urinary system
- Impaired function of the thyroid
- Impaired function of the prostate
- Diabetes
- Alcoholism
- Increased restlessness
- Viral jaundice
- If you are pregnant

If you are taking, or have recently taken, other medicines, including non-prescription medicines and food supplements and vitamins, tell the doctor or pharmacist. Especially 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).
- Anticoagulants, especially warfarin.
- Antidepressants (including monoamine oxidase inhibitors [MAOI] – see above, or tricyclic antidepressants).
- Cough and cold medicines (e.g., other medicines for nasal congestion).
- Medicines to treat asthma (from the sympathomimetic group).
- Methyldopa or other antihypertensives (e.g., beta blockers, alpha blockers or vasodilators) and heart medicines.
- Medicines 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 the level of fats in the blood).
- 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.

Pregnancy and breastfeeding

If you are pregnant consult the doctor before commencing treatment with the medicine.

If you are breastfeeding do not use this medicine.

Use in children

This medicine is intended for adults and 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 unless otherwise instructed by the doctor:

Adults and children 12 years of age and above:

2 liquigel capsules up to 4 times a day.

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

Patients above the age of 60 years must 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 there was no pain relief within 5 days despite use of the medicine.

Directions for use

Do not chew!

Swallow the capsule 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 pain, flatulence, excessive 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 each time you take medicine. Wear glasses if you need them.

4. SIDE EFFECTS

As with any medicine, use of Acamol Tsinun Liquigel Day may cause side effects, such as dizziness, lack of appetite, dry mouth, difficulty passing urine (in men only), nervousness, sleeplessness or tension in some users. 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 difficulty breathing or swallowing.
- 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).
- If signs of changes in the blood system occur, such as: unexplained tiredness, bleeding, bruises, development of inflammations more easily.
- Severe pancreatitis (as a result of overdose).

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

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine must be kept in a closed 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.

6. FURTHER 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.

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

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

Manufacturer and license holder:

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

This leaflet was checked and approved by the Ministry of Health in October 2013.

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

125.99.30511.00
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