

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

The medicine is dispensed without a doctor's prescription

TEVA-COLD TABLETS

TEVA-COLD CAPLETS

The active ingredients and their quantities in each tablet/caplet:

Paracetamol	300 mg
Caffeine anhydrous	30 mg
Phenylephrine hydrochloride	10 mg
Chlorpheniramine maleate	2 mg

For information on the inactive and allergenic ingredients in the preparation, see section 2 – "Important information regarding some of the ingredients of the medicine" and section 6 – "Further Information".

Read the 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.

Take the medicine according to the instructions given in this leaflet (section 3) in the section on dosage. Consult the pharmacist if you need further information.

Refer to the doctor if the symptoms of the illness worsen or if there is no improvement after 3-5 days.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended to relieve cold symptoms, sinus congestion and allergic rhinitis accompanied by fever and pain.

Therapeutic group:

- Paracetamol – analgesic and antipyretic.
- Caffeine anhydrous – xanthine alkaloid, central nervous system stimulant.
- Phenylephrine hydrochloride – sympathomimetic, decongestant for the nose and ears.
- Chlorpheniramine maleate – antihistamine.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to paracetamol, caffeine, phenylephrine, chlorpheniramine maleate or to any of the additional ingredients contained in the medicine (see section 6 – "Further Information").
- In the past you developed an allergic reaction after using antihistamines.
- You suffer from problems of the kidneys, liver, from hyperthyroidism, from diabetes, from high blood pressure or from heart disease.
- You suffer from pheochromocytoma or from glaucoma.
- You are taking tricyclic antidepressants (for example, imipramine or amitriptyline).
- You are taking or have taken during the past two weeks an antidepressant of the monoamine oxidase inhibitors (MAOI) group (for example, moclobemide).
- You are taking a beta-blocker (for example, atenolol).
- You are taking other paracetamol-containing medicines – see "Special warnings" in this section.
- You are taking other antihistamine-containing medicines, including other medicines for treatment of flu, cough, cold, or other decongestants.
- You are pregnant or breastfeeding.

Special warnings regarding use of the medicine

- If you have previously developed skin side effects as a result of taking preparations containing paracetamol, 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 higher dosage than recommended or for a prolonged period of time.
 - drinking alcoholic beverages during the course of treatment.
 - taking additional medicines that affect liver function.
- Do not take additional antipyretics and analgesics or cold medicines without consulting a doctor or pharmacist, in order to prevent paracetamol overdose/toxicity.
- Avoid taking a high dosage of this medicine (even if this is within the recommended dosage range) when fasting.
- Do not use this medicine frequently without consulting a doctor.

Before treatment with Teva-Cold, tell the doctor if you suffer, or have suffered in the past, from:

- a disease of the blood vessels such as Raynaud's phenomenon
- an enlarged prostate gland
- heart disease or a disease connected with blood circulation

Refer to the doctor immediately if you have a combination of these symptoms.

During the course of treatment with the medicine, refer to the doctor immediately if:

- you have a severe infection or disease, including severe kidney failure or sepsis (a condition in which bacteria and their toxins circulate in the blood and lead to organ damage), or you are suffering from malnutrition, chronic alcoholism, or if you are taking flucloxacillin (antibiotic).
- metabolic acidosis (a blood and body fluid disturbance) – severe condition has been reported in patients when they took the maximum daily dosage of paracetamol for a prolonged period or when paracetamol was taken with flucloxacillin. Symptoms of metabolic acidosis include: severe breathing difficulties, including deep and rapid breathing, sleepiness, nausea and vomiting, loss of appetite.
- extremely high blood pressure.
- epilepsy.
- glaucoma.
- liver or kidney disease.
- bronchitis, asthma, bronchiectasis (widening of the airways) or chronic lung disorders (difficulty in breathing and a persistent cough).

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:

- Metoclopramide (Pramin) or domperidone (for treatment of nausea or vomiting)
- Ergotamine and methysergide (for migraines)
- Cholestyramine (to reduce blood cholesterol)
- Antihypertensives
- Medicines for suppressing or increasing appetite
- Antidepressants, including tricyclic antidepressants (for example, amitriptyline)
- Antidepressants of the monoamine oxidase inhibitors type, or if you have taken such a medicine within the past two weeks
- Medicines for heart disease (for example, digoxin)
- Anticoagulants (for example, warfarin)
- Phenytoin (for epilepsy)
- Medicines for treatment of anxiety
- Sleeping tablets
- Anti-cough and anti-cold medicines
- Antihistamines
- Flucloxacillin (antibiotic), due to a serious risk of blood and body fluid disturbances (metabolic acidosis), which require immediate treatment (see in section 2 – "Before treatment with Teva-Cold").

Use of Teva-Cold and food

Take the medicine with a meal.

Do not take this medicine with a large quantity of caffeinated beverages, such as coffee, tea or cola. High caffeine intake can cause difficulty sleeping, shaking, and an uncomfortable feeling in the chest.

Use of Teva-Cold and alcohol consumption

Do not drink alcoholic beverages during the course of treatment with the medicine.

Pregnancy and breastfeeding

Do not use Teva-Cold if you are pregnant or breastfeeding, except under the instructions of a doctor.

Driving and operating machinery

Use of this medicine may impair alertness and cause dizziness or blurred vision and therefore requires that caution be exercised when driving a vehicle, operating dangerous machinery and when engaging in any activity that requires alertness. Children should be warned against riding bicycles or playing near the road and the like.

Important information regarding some of the ingredients of the medicine

The preparation contains lactose and may cause allergic reactions in people sensitive to lactose. Consult the doctor if you have been told that you have an intolerance to certain sugars.

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The recommended dosage is generally:

Adults: one tablet/caplet every 4 hours (as needed).

Children aged 6-12 years: one tablet/caplet up to 3 times a day.

Refer to a doctor if the disease symptoms worsen or do not improve after 3-5 days.

Do not exceed the recommended dose.

Directions for use

Take the medicine with a meal. Swallow the medicine with water.

Do not chew, crush or halve.

If you took an overdose or if a child has accidentally swallowed the medicine,

immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you. Even if you feel well despite taking an overdose, immediate treatment is essential. **due to risk of development of severe liver damage.**

If you forgot to take the medicine at the scheduled time, take a dose as soon as you remember, but never take two doses together!

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

If you have further questions regarding use of the medicine, consult a doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Teva-Cold may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Serious side effects:

Stop using the medicine and refer to the doctor immediately if the following rare side effects occur:

- Allergic reactions which may be severe, such as: skin rash and itching sometimes accompanied by swelling of the mouth or face or shortness of breath, fainting/loss of consciousness (rare to very rare).
- Skin rash or peeling, or mouth ulcers.
- Breathing problems (more likely if you have experienced such problems in the past after taking other painkillers, such as ibuprofen or aspirin).
- Unexplained signs of bruising or bleeding.
- Recurring fever or infections.
- Nausea or vomiting, sudden weight loss, loss of appetite and severe abdominal pains, yellowing of the skin and eyes (hepatitis).
- Visual disturbances (rare, but more common if you have glaucoma).
- Unusually rapid pulse or a sensation of an unusually fast or irregular heartbeat.
- Difficulty in passing urine (more likely to occur in men with an enlarged prostate).

Severe skin side effects may occur even if you have taken preparations containing the active ingredient paracetamol in the past and did not suffer from side effects.

Very common side effects (affect more than 1 in 10 patients):

- Drowsiness, sedation
- Disturbances in concentrating, lack of coordination, dizziness, headache
- Blurred vision
- Nausea or vomiting, dry mouth
- Fatigue

Additional side effects:

Refer to the doctor if you suffer from:

- Increase in blood pressure
- Difficulty sleeping, nervousness, anxiety
- Abdominal pain, diarrhea, indigestion
- Confusion, over-excitability, nightmares, depressed mood
- Low blood pressure
- Thick phlegm
- Rash, itchiness, sensitivity to sunlight
- Muscle spasms, muscle weakness
- Chest tightness
- Ringing in the ears
- Low blood count

A serious condition that can cause the blood to become more acidic (called metabolic acidosis) in patients with severe diseases who are taking Teva-Cold (see in section 2 – "Before treatment with Teva-Cold").

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

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

• Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by 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 dark place, below 25°C.**

• Do not discard medicines into the wastewater or waste bin. Ask the pharmacist how to dispose of medicines no longer in use. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredients, the medicine also contains:

Lactose monohydrate, povidone, sodium starch glycolate, colloidal silicon dioxide, magnesium stearate, hydrogenated vegetable oil, eudragit E 100.

Coating composition:

Hypromellose, titanium dioxide, polyethylene glycol, quinoline yellow aluminium lake, iron oxide yellow, indigo carmine aluminium lake [FD&C blue no. 2].

Each tablet/caplet contains 26.5 mg lactose.

What the medicine looks like and the contents of the package

Tablet appearance – Round, yellow-greenish film-coated tablets.

Caplet appearance – Oblong, smooth tablets with a yellow-greenish film-coating.

Each package contains 20 tablets/caplets. Not all package types may be marketed.

Name of Manufacturer and License

Address:

Teva Israel Ltd.,
124 Dvora HaNev'ia St., Tel Aviv 6944020

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

Tablets: 156.61.34935

Caplets: 059.74.21484

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TEVA-COLD TAB-CAPL PL SH0325

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