

**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 the list of inactive ingredients, see section 6 – "Further Information".

Read this 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.

If there is no improvement in your condition after 3-5 days of treatment, refer to the doctor.

1. WHAT IS THE MEDICINE INTENDED FOR?

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

Therapeutic group

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

2. BEFORE USING THE MEDICINE

❑ Do not use this medicine if:

- you are sensitive (allergic) to the active ingredients or to any of the other ingredients of the medicine
- you developed an allergic reaction in the past 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 pregnant or breastfeeding
- you are taking monoamine oxidase inhibitors (MAOIs) for depression, or are within 14 days of discontinuing treatment with them
- you are taking tricyclic antidepressants
- you are taking beta blockers
- you are taking other paracetamol-containing medicines – see "Special warnings" under this section
- you are taking other antihistamine-containing medicines, including other medicines for treatment of flu, cold or other decongestants

Special warnings regarding use of the medicine

- If you have 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 effects will not recur.
- The medicine contains paracetamol, which may cause liver damage when:
 - Given at a higher dosage than recommended or for a prolonged period.
 - 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 the doctor or pharmacist, to prevent paracetamol overdose/toxicity.
- Avoid taking a high dosage of this medicine (even if it is within the recommended dosage range) when fasting.
- Do not use this medicine frequently without consulting a doctor.
- The medicine may disrupt allergy test results; therefore, stop taking it 4 days before performing these tests.
- Before any surgery or performing tests, inform the doctor that you are taking this medicine.
- Elderly patients may be sensitive to decongestants.

• Before treatment with the medicine, tell the doctor if you suffer, or have suffered in the past, from impaired function of:

- the respiratory system (e.g., asthma)
- blood vessels (e.g., Raynaud's disease)
- the eyes
- alcoholism or jaundice
- the digestive system (e.g., ulcer)
- the prostate
- tendency to retain urine
- epilepsy – the medicine contains chlorpheniramine, which has anticholinergic effects and should be used with caution in epilepsy patients

❑ If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. It is particularly important to inform the doctor or pharmacist if you are taking:

- Aspirin and salicylates
- Medicines which affect the central nervous system (e.g., sedatives, analgesics and antipyretics, hypnotics, medicines for treatment of Parkinson's, antiepileptics [e.g., phenytoin])
- Anti-cough and anti-cold medicines
- Medicines for treatment of asthma
- Non-steroidal anti-inflammatory drugs
- Antidepressants of the monoamine oxidase inhibitors type, or within 14 days of discontinuing treatment with them
- Antidepressants, including tricyclic antidepressants
- Aminoglycoside antibiotics (e.g., gentamicin)
- Anticoagulants (e.g., warfarin)
- Metoclopramide or domperidone (for treatment of nausea, vomiting and other stomach problems)
- Ergotamine
- Cholestyramine (to reduce excess blood fats)
- Preparations which accelerate production of enzymes in the liver (e.g., barbiturates, phenytoin or carbamazepine)
- Antihypertensives (e.g., beta blockers)
- Appetite suppressants
- Medicines for heart disease (e.g., digoxin)
- Antihistamines
- Lopinavir (for treatment of viral infections)

❑ Use of Teva-Cold and food

Take the medicine with a meal.

Do not take this medicine with large quantities 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 wines or alcoholic beverages during the course of treatment with this medicine.

❑ Pregnancy and breastfeeding

Do not use Teva-Cold if you are pregnant or breastfeeding.

❑ Driving and operating machinery

Use of this medicine may impair alertness and cause dizziness 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 medicine contains lactose and may cause allergic reactions in people sensitive to lactose. Consult the doctor if you have been told in the past 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 how to use the medicine.

The recommended dosage unless instructed otherwise by the doctor:

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

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

Do not exceed the recommended dose.

Directions for use

Take the medicine with a meal. Swallow the medicine with a little 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 the 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:

- you are suffering from diarrhea, nausea, abdominal pain
- allergic effects occur: difficulty breathing, difficulty swallowing, swelling of the lips, tongue or face, itching and rash (urticaria), sensitivity to sunlight
- Paracetamol can, in rare cases, cause the occurrence 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 and did not suffer from side effects. If skin side effects occur, stop treatment and refer to the doctor immediately
- you are suffering from liver problems (yellowing of the skin or eyes), increased tendency to bleed and bruise, blood problems such as anemia, severe fatigue
- you experience increased thirst or appetite, dizziness, fainting (low blood pressure), chest tightness, thicker phlegm
- rash or skin peeling or mouth ulcers occur
- you are suffering from sudden weight loss, lack of appetite
- you are suffering from visual disturbances
- you are suffering from fast heart rate or from a feeling of irregular heart rate
- you are suffering from breathing difficulties
- you are suffering from a difficulty in passing urine (more likely to occur in men with an enlarged prostate)
- muscle weakness, seizures, lack of coordination occur

Refer to a doctor if:

You are suffering from increased blood pressure

Additional side effects:

- drowsiness
- dry mouth, eyes and nose
- ringing in the ears
- depression or low mood, nightmares, confusion, over-excitability, hyperactivity (especially in children), restlessness

If a side effect occurs, if any of the side effects worsen, or if you are suffering from a side effect not mentioned in the leaflet, consult 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 without an 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 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, hypromellose, titanium dioxide, polyethylene glycol, quinoline yellow aluminium lake, iron oxide yellow, indigo carmine aluminium lake [FD&C blue no. 2], colloidal silicon dioxide, magnesium stearate, hydrogenated vegetable oil, Eudragit E 100.

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.

Manufacturer, license holder and address:

Teva Pharmaceutical Industries Ltd., P.O.B. 3190, Petach Tikva

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

Tablets: 156.61.34935.00

Caplets: 059.74.21484.02

The format of this leaflet was determined by the Ministry of Health and its content was checked and approved by the Ministry of Health in October 2013, and updated in accordance with the Ministry of Health guidelines in January 2020.