

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

The medicine is dispensed without a doctor's prescription

Paramol Target, Caplets

Each caplet contains:

Acetylsalicylic acid 250 mg

Paracetamol 250 mg

Caffeine (anhydrous) 65 mg

For the list of inactive and allergenic ingredients in the preparation, see 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 preparation in accordance with the instructions in section 3 – **“How should you use the medicine?”**. Consult a pharmacist if you need further information. Refer to the doctor if the symptoms of the ailment worsen or are not improving after 5 days of treatment for pain or after 3 days of treatment for pain accompanied by fever (see section 3 **“How should you use the medicine?”**).

1. WHAT IS THE MEDICINE INTENDED FOR?

Paramol Target is intended for temporary relief of the pain of headache, mild to moderate pain associated with migraine headache, pain of menstrual discomfort and pain accompanied by fever.

Therapeutic group:

Acetylsalicylic acid – non-steroidal anti-inflammatory drug (NSAID).

Paracetamol – analgesic and antipyretic.

Caffeine – xanthine alkaloid, central nervous system stimulant.

2. BEFORE USING THE MEDICINE

Do not use Paramol Target if:

- **you are sensitive (allergic) to the active ingredients or to any of the additional ingredients contained in the medicine (see section 6 “Further information”).**
- **you have had an allergic reaction in the past to other medicines used to treat pain, inflammation or fever, such as acetylsalicylic acid, salicylate, diclofenac or ibuprofen.**
Symptoms of an allergic reaction may include: asthma, wheezing or shortness of breath, skin rash or hives, swelling of the face or tongue, runny nose. If you are uncertain, ask your doctor or pharmacist.
- **you have a stomach or intestinal ulcer, or you have a history of digestive (peptic) ulcers.**
- **you noticed blood in the stools or black stools (symptoms of gastrointestinal bleeding or perforations).**
- **you are suffering from hemophilia or other blood disorders.**

- you are suffering from **severe heart, liver and kidney problems**.
- you are taking **more than 15 mg methotrexate per week** (see “**Drug interactions**” section).
- you are **in the last three months of pregnancy** (see “**Pregnancy, breastfeeding and fertility**” section).

Special warnings regarding use of the medicine

Before commencing treatment with Paramol Target, tell the doctor if:

- you have not been diagnosed in the past as suffering from migraines, since possibly serious conditions related to the brain or nervous system must be ruled out before treatment.
- you suffer **from a migraine so acute that it necessitates bedrest**, or if you have a headache that is different from your usual migraines, or if you suffer **from vomiting together with the migraine headaches**.
- you began to suffer **from headaches after or due to a head injury, exertion, cough or bending over**.
- you have chronic headaches (fifteen days or more per month for more than three months), or if you experienced the first headache after the age of 50.
- you are suffering from liver or kidney problems, underweight or malnutrition or if you regularly drink alcohol. You may need to fully abstain from use of the product or limit paracetamol use.
- you are suffering from a severe infection, severe malnutrition, or severe underweight or you constantly drink alcohol. This may increase the risk of metabolic acidosis. Signs of metabolic acidosis: breathing difficulties (deep, rapid breathing), nausea, vomiting and loss of appetite. Refer to a doctor immediately if you suffer from these symptoms.
- you are suffering from a hereditary condition called G6PD (glucose-6-phosphate dehydrogenase) enzyme deficiency which affects the red blood cells and may cause anemia, jaundice or spleen enlargement upon exposure to certain foods and medicines such as certain anti-inflammatories [such as acetylsalicylic acid (aspirin)] or cause other illnesses.
- you have suffered in the past **from gastrointestinal problems** such as stomach ulcer, bleeding or black stools. If you have had abdominal discomfort or heartburn after taking analgesics or anti-inflammatories.
- you are suffering **from bleeding disturbances or abnormal vaginal bleeding** unlike menstruation (such as unusually prolonged and heavy menstrual bleeding).
- you recently had **surgery** (including minor surgery such as dental surgery) or you are about to have surgery in the next seven days.
- you are suffering **from adult asthma, hay fever (allergic rhinitis), nasal polyps, a chronic respiratory disease or you develop allergic symptoms** (such as skin reactions, itching, urticaria).
- you are suffering **from gout, diabetes, hyperthyroidism, heart rate disturbances, uncontrolled hypertension, impaired kidney or liver function**.
- you are suffering **from alcohol addiction** (see sections “**Use of the medicine and food**” and “**Use of the medicine and alcohol consumption**” below).

- you are **taking other medicines that contain acetylsalicylic acid (aspirin) or paracetamol**, or other medicines, as certain medicines may interfere with Paramol Target and cause side effects (see “**Drug interactions**” below).
- you are **at risk of dehydration** (i.e., vomiting, diarrhea, or before or after major surgery).
- you are **under 18 years of age**. There is a possible connection between acetylsalicylic acid (aspirin) and Reye’s syndrome when given to children and adolescents. Reye’s syndrome is a rare syndrome that affects the brain and liver and may be fatal. For this reason, do not use Paramol Target in adolescents and children under 18 years of age without explicit instruction from the doctor.

Additional warnings

As with any type of headache analgesics, taking Paramol Target too often (i.e., more than ten days per month for this medicine) when there are chronic headaches (fifteen days or more per month), for more than three months, may worsen your headache or migraine.

If you think that this may be the case, refer to your doctor for advice. You may have to stop taking Paramol Target in order to resolve the problem.

Paramol Target may reduce symptoms of infection (such as headache, high fever) and therefore may make it harder to detect the infection. If you do not feel well and you need to refer to the doctor, remember to tell him that you are taking Paramol Target.

Children and adolescents

Paramol Target is not intended for children and adolescents under 12 years of age.

Tests and follow-up

Paramol Target may affect results of lab tests. If you were asked to perform a blood, urine or other lab test, remember to tell them that you are taking Paramol Target.

Drug interactions

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

- **Any other preparation containing paracetamol, acetylsalicylic acid (aspirin), or any other pain reliever/fever reducer.**
- **Medicines used to prevent blood clotting**, such as oral anticoagulants (e.g., warfarin), heparin, thrombolytics (e.g., streptokinase), or other antiplatelets (ticlopidine, clopidogrel, cilostazol).
- **Corticosteroids** (used to relieve inflammation).
- **Barbiturates and benzodiazepines** (for the treatment of anxiety and insomnia).
- **Lithium, selective serotonin reuptake inhibitors (SSRI) or fluvoxamine** (to treat depression).
- **Sulphonyl-urea and insulin** (to treat diabetes).
- **Methotrexate** (to treat certain types of cancer, arthritis or psoriasis).
- **Certain medicines for the treatment of infection** (such as rifampicin, isoniazid, chloramphenicol, ciprofloxacin or pipemidic acid).

- **Levothyroxine** (for the treatment of hypothyroidism).
- **Metoclopramide** (for the treatment of nausea and vomiting).
- **Antiepileptics.**
- **Medicines for the treatment of hypertension and heart failure.**
- **Diuretics** (to increase urine production and reduce excessive fluids).
- **Medicines for the treatment of gout.**
- **Oral contraceptives.**
- **Zidovudine** (for the treatment of human immunodeficiency virus).
- **Medicines for the treatment of slow gastric emptying** (e.g., propantheline).
- **Clozapine** (for the treatment of schizophrenia).
- **Sympathomimetic medicines** (to raise blood pressure or for the treatment of nasal congestion).
- **Anti-allergy medicines** (for the treatment or relief of allergies).
- **Theophylline** (for the treatment of asthma).
- **Terbinafine** (for the treatment of fungal infections).
- **Cimetidine** (for the treatment of heartburn and peptic ulcer).
- **Disulfiram** (for the treatment of alcohol dependency).
- **Nicotine** (for smoking cessation).
- **Cholestyramine** (for the treatment of high cholesterol levels).
- **Flucloxacillin** (antibiotic), due to serious risk of blood and fluid disturbances (high anion gap metabolic acidosis) which requires emergency treatment and may occur especially in cases of severe kidney injury, sepsis (a condition in which bacteria and their toxins circulate in the blood and lead to organ damage), malnutrition, chronic alcoholism and in cases of use of the maximal daily doses of paracetamol.

Use of the medicine and food

The recommended dose of this medicine contains a quantity of caffeine similar to that in a cup of coffee. When using the medicine, limit caffeine consumption of caffeine-containing medicines, foods and beverages, as excess caffeine may cause irritability, restlessness, insomnia and sometimes rapid heart rate.

Use of the medicine and alcohol consumption

Abstain from consuming alcohol while using this medicine. If you consume three or more alcoholic beverages per day, ask your doctor if you should take this medicine or other analgesics/antipyretics. Paracetamol and acetylsalicylic acid (aspirin) may cause liver damage and stomach bleeding.

Pregnancy, breastfeeding and fertility

This medicine is not recommended during pregnancy.

If you are pregnant, think you may be pregnant or are planning to become pregnant, **tell your doctor and do not take Paramol Target.**

Pregnancy – third trimester

It is especially important not to take Paramol Target during the last three months of pregnancy, since it may harm the fetus or cause problems during labor. This may cause fetal kidney or heart problems. This may affect your or your baby's tendency to bleed or cause a later-than-expected delivery.

Pregnancy – first and second trimester

Due to the aspirin content, this medicine should not be taken during the first 6 months of pregnancy, unless the treatment is essential and only when recommended by your doctor.

If you need treatment during this period, use the lowest dosage for the shortest period. If you took this medicine for more than a few days in week 20 or later in the pregnancy, aspirin may cause kidney problems in the unborn baby, that leads to low levels of amniotic fluid which envelops your baby or to narrowing of blood vessels in your baby's heart (ductus arteriosus).

If you need treatment for more than a few days, the doctor may recommend additional follow-up tests.

Paramol Target is not recommended when breastfeeding.

Consult the doctor or pharmacist before using any medicine.

Paramol Target belongs to a group of medicines (NSAIDs) that may impair fertility in women. This effect is reversible when discontinuing use of the medicine.

Driving and operating machinery

Use of Paramol Target has no known effect on your ability to drive and operate machinery.

If you notice side effects such as dizziness or drowsiness, avoid driving and operating machinery. Tell your doctor as soon as possible.

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 medicine. The recommended dosage is generally:

For treatment of migraine-associated headache:

Adults: two caplets. If the medicine was taken for a migraine and there was no improvement or it worsened after the first dose, consult a doctor.

Children under 18 years of age: Consult a doctor.

Do not take the medicine for more than 48 hours for a migraine.

For headaches, menstrual pains and pain accompanied by fever:

Adults and children over 12 years of age: 2 caplets every 6 hours.

Pain relief may be achieved within 15 minutes of taking the dose.

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

Do not exceed the recommended dose.

Do not use the medicine for more than 5 days for pain or 3 days for pain accompanied by fever without consulting a doctor.

Elderly:

There is no recommendation for a specific dosage. If you have a low body weight, consult the doctor or pharmacist.

Swallow the caplet whole with a full glass of water.

Do not halve or crush the caplet. There is no information about halving/crushing/chewing.

Do not lie down for 15-30 minutes after taking the medicine.

Paramol Target caplets contain acetylsalicylic acid (aspirin), paracetamol and caffeine. Do not take more than the recommended dosage and do not take other medicines that may contain these ingredients or other ingredients used to treat pain, inflammation or high fever (NSAIDs) while using Paramol Target.

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. Immediate medical treatment is critical **considering the possible irreversible risk to the liver** because of paracetamol. Do not wait until onset of symptoms since, at first, the overdose may not cause detectable symptoms.

If symptoms of an overdose occur, they may be:

- for **acetylsalicylic acid (aspirin)**: dizziness, ringing in the ears, deafness, sweating, hyperventilation, high fever, nausea, vomiting, headache, confusion or restlessness, circulatory collapse (of the blood circulation) or respiratory failure.
- for **paracetamol**: the first symptoms that may appear – nausea, vomiting, lack of appetite, paleness, sleepiness, sweating and afterwards abdominal pain.
- for **caffeine**: anxiety, irritability, restlessness, insomnia, excitement, muscle contraction, confusion, convulsions, hyperglycemia, tachycardia (rapid heart rate) or arrhythmia.

Even if these symptoms do not occur or if they disappear, it is essential that you seek medical assistance immediately.

If you forgot to take the medicine

Take the medicine as soon as you remember, but do not take a double dose to compensate for the forgotten dose.

Do not take more than 8 caplets within a 24-hour period.

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 Paramol Target 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.

Discontinue use and refer to the doctor immediately if you experience one or more of the following serious side effects:

- An allergic reaction with swelling of the face, lips, mouth, tongue, or throat. This may cause difficulty swallowing, wheezing, breathing difficulties, and a sense of chest tightness (signs of asthma). You may also have a rash or itching, or experience fainting.
- Skin rash (including urticaria, itching), redness of the skin, blisters on the lips, eyes or mouth, peeling of the skin, sores, mouth ulcers.
- Stomach or intestinal bleeding, stomach or intestinal ulcer, which may be accompanied by acute abdominal pain, bloody vomit, bloody or black stools, or bloody vomit. As with treatment with all analgesics and antipyretics, these

effects may occur at any time during the course of treatment, with no prior history, and may be fatal. This side effect is especially serious in the elderly.

- Yellowing of the skin or eyes (signs of liver failure).
- Dizziness or mild headache (signs of low blood pressure).
- Irregular heart rate.
- You experienced breathing problems with acetylsalicylic acid or an NSAID and you experience a similar reaction with Paramol Target.
- Unexplained bruises or bleeding.
- Increased number of nosebleeds or bruises.
- Swelling or water retention.
- Ringing in the ears or temporary hearing loss.
- Behavioral changes, nausea and vomiting – this may be a sign of Reye's syndrome.

Additional side effects

The following side effects have been reported in 16 clinical trials conducted in more than 4,800 patients.

Tell your doctor if you notice any of these side effects:

Common side effects – effects that occur in up to 1 user in 10:

- Nervousness, dizziness
- Nausea, abdominal discomfort

Uncommon side effects – effects that occur in up to 1 user in 100:

- Insomnia, tremor, numbness, headache
- Dry mouth, diarrhea, vomiting
- Tiredness, a feeling of nervousness
- Increase in the heart rate

Rare side effects – effects that occur in up to 1 user in 1,000:

- Sore throat, swallowing difficulties, numbness or tingling around the mouth, excess saliva
- Decreased appetite, altered taste
- Anxiety, euphoria, tension
- Attention disorders, memory loss, changes in coordination (coordination of movements)
- Sense of pain in the cheeks and forehead
- Eye pain, visual disturbances
- Hot flashes, problems in peripheral blood vessels (such as in the arms or legs)
- Nosebleed, slow and shallow breathing, runny nose
- Burping, flatulence (gas)
- Excessive sweating, itching, itchy rash, increased skin sensitivity
- Muscle, bone or joint rigidity; neck pain, backache, muscle cramps
- Weakness, chest discomfort

Side effects with unknown frequency (effects whose frequency has not yet been determined):

The following side effects have also been reported since the beginning of marketing of the medicine. In general, the frequency during post-marketing surveillance can not be determined precisely; therefore, the frequency is indicated as “unknown”:

- Restlessness, general bad or abnormal feeling

- Somnolence, migraine
- Skin redness, rash. Very rare cases of serious skin reactions have been reported.
- Palpitations, shortness of breath, sudden breathing difficulties and a feeling of tightness in the chest with wheezing or coughing (asthma)
- Abdominal pain, abdominal discomfort after meals
- Elevated liver enzymes
- Nasal swelling and irritation
- Kidney problems

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 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>

In addition, they can be reported to Padagis via the following address: padagis.co.il

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 and sight of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from a 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.
- **Storage conditions:** Store at a temperature below 25°C.
- Can be used for 9 months after first opening, but not later than the expiry date.
- Do not dispose of medicines in the wastewater or household waste bin. Ask the pharmacist how to dispose of medicines that are not in use. These measures will help protect the environment.

6. FURTHER INFORMATION

- **In addition to the active ingredients, the medicine also contains:** Microcrystalline cellulose, hypromellose, stearic acid, crospovidone, titanium dioxide, pregelatinized starch, propylene glycol, povidone, carnauba wax, saccharin sodium, blue No. 1 FD&C lake.
- **What the medicine looks like and the contents of the package:** The medicine is provided in small bottles containing 24 or 50 white caplets with “L374” debossed on one side. Not all package sizes may be marketed. The package contains a desiccant. Do not swallow the desiccant or take it out of the bottle.
- **Registration holder and address:** Padagis Israel Agencies Ltd., 1 Rakefet St., Shoham.
- **Manufacturer and address:** Perrigo company, Allegan, Michigan, USA.
- Revised in March 2025.

- **Registration number of the medicine in the National Drug Registry of the Ministry of Health: 14079.32024**

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