

PARAMOL PLUS, CAPLETS



Patient package insert according to Pharmacists' Regulations (Preparations), 1986.

This medicine can be sold without a physician's prescription

Each caplet contains:

Paracetamol	500 mg
Caffeine	50 mg

For list of excipients, please see section 6.

Read this entire leaflet carefully before you start taking this medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask your physician or pharmacist.

This medicine is dispensed without a physician's prescription and is intended for adults and children over 12 years only. Under this age, refer to your physician. Use it in the correct manner. Consult your physician or your pharmacist if you need additional information.

Refer to your physician, if the fever lasts for more than 3 days or if the symptoms of your illness get worse or do not improve within 3 days despite the use of the medicine or in any situation where new symptoms appear.

1. What is the medicine used for?

Paramol Plus is intended for pain relief and fever reduction, caused due to various reasons such as: headache, toothache, cold, flu, rheumatic and menstrual pain.

Therapeutic group:

Paracetamol - pain reliever and fever reducer.
Caffeine - xanthine derivative, helps relieve pain.

2. Before you take the medicine:

Do not use the medicine if:

- you are under 12 years old.
- you are hypersensitive (allergic) to the active ingredients (paracetamol, caffeine) or to any of the other ingredients of this medicine, or to any food or drinks containing caffeine such as: tea, coffee, cola and chocolate.
- You suffer from high blood pressure, irregular heart rate or anxieties.
- you are taking medicines from the following groups: medicines for high blood pressure, for the treatment of depression including monoamine oxidase inhibitors (MAOIs); medicines that cause drowsiness or stimulants; medicines for the treatment of anxiety; ephedrine containing medicines (such as cold medicines); theophylline (for breathing problems); thyroxine (for thyroid problems); disulfiram (for alcoholism).
- you are pregnant or breastfeeding.

Special warnings regarding the use of this medicine:

- Before taking **Paramol Plus** tell your physician if:
 - you suffer or have suffered in the past from impaired function of: the heart and/or blood vessels, the liver (including alcoholic liver disease), the kidney/ urinary tract, sleeping disturbances, alcoholism, jaundice.
 - you are sensitive to xanthines (used mainly for the treatment of asthma and other lung diseases).
 - you are sensitive to any food or medicine.
 - you suffer from arthritis and have to take pain

- relievers every day.
- Do not use this medicine frequently without consulting your physician.
- Avoid taking a high dosage (even if at the recommended limit) of this medicine while fasting.
- This product contains paracetamol that may cause damage to the liver in the following cases: when administered at a dosage higher than recommended or for an extended period, when consuming alcoholic beverages during the treatment period or when taking additional medicines that affect the function of the liver.
- Do not take additional medicines for fever reduction and relief of pain or other cold medicines, without consulting your physician or pharmacist, in order to prevent paracetamol overdose/ toxicity.
- Do not take additional medicines of the "Paramol" group and/ or any other paracetamol-containing products.
- If you have developed dermal side effects in the past resulting from taking products containing paracetamol, do not take products containing paracetamol to avoid severe skin manifestations from recurring.
- If you are about to undergo cardiac tests, you should stop treatment 24 hours prior to the tests, as it may affect the test results.

Please tell your physician or pharmacist if you are taking or have recently taken any other medicines, including non-prescription drugs and nutrition supplements. Especially inform your physician or pharmacist if you are taking:

- drugs affecting the central nervous system such as: appetite suppressants, amphetamines, medicines for the treatment of Parkinson's disease, antidepressants such as selective serotonin reuptake inhibitors (SSRIs), bupropion (e.g. for aiding smoking cessation), pemoline and methylphenidate (e.g. for attention deficit disorders) and hypnotics.
- anticoagulants (such as: warfarin)
- medicines that increase liver enzyme activity such as barbiturates, phenytoin or carbamazepine (used mainly for epilepsy, seizures and psychiatric problems), rifampicin (an antibiotic), probenecid (for the treatment of gout).
- aspirin or other salicylates, additional pain relieving or fever reducing medicines and non-steroidal anti-inflammatory drugs.
- medicines for the treatment of sinus problems, anti-allergics (such as for hay fever) and xanthines, methoxyflan (for painless), piperidine acid (for infections).
- metoprololam or domperidone (for the treatment of nausea, vomiting and other stomach problems); cholestyramine (for reduction of blood lipid levels) and other caffeine containing products.
- do not take this medicine with any other paracetamol-containing medicines (If you are not sure whether the medicine you are taking contains paracetamol, consult your physician or pharmacist).
- medicines for hypertension, monoamine oxidase inhibitors (MAOIs), medicines that cause drowsiness or stimulants, medicines for the treatment of anxiety, ephedrine containing medicines, thyroxine, disulfiram - see also section "Do not use the medicine if".

Use of this medicine and food:

Do not consume coffee, tea, cola, chocolate or caffeinated beverages during

treatment with this medicine. Increased consumption of caffeine can cause sleeping difficulties, tremor and a rapid heartbeat.

Use of this medicine and alcohol consumption: Do not drink alcoholic beverages during the period of treatment with this medicine due to the increased risk of liver damage.

Pregnancy and breastfeeding:

Do not use this medicine if you are pregnant or breastfeeding.

Use in children:

This medicine is intended for adults and children over 12 years only, see section 3.
Parents should report to the physician about any side effects and any additional medicine given to the child.

3. How to use this medicine

Check with your physician or pharmacist if you are not sure.

Unless otherwise instructed by the physician, the recommended dosage is:

Adults and children over 12 years of age: 1-2 caplets every 4-6 hours as needed. Do not exceed the dosage of 8 caplets per day.

Do not exceed the dose recommended by the physician or pharmacist.

Swallow the medicine with water.

May be halved or crushed for ease of swallowing, however the entire dose should be swallowed.

If you have accidentally taken a higher dosage or if a child has accidentally swallowed the medicine, proceed immediately to a physician or a hospital emergency room and bring the package of the medicine with you! Do not induce vomiting unless explicitly instructed to do so by your physician. Even if you feel well, immediate treatment is essential because of the risk of developing serious damage to the liver.

Side effects may occur such as diarrhea, excessive sweating, poor appetite, nausea or vomiting, stomach cramps or pain, swelling, pain or tenderness in the upper abdomen and they may not reflect the damage to the liver.

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

4. Side effects:

Like all medicines, **Paramol Plus** can cause side effects, although not everybody gets them. Do not be alarmed while reading the list of side effects. You may not suffer from any of them.

The side effects may be more serious in the elderly.

Serious side effects:

Stop use of this medicine and refer to your physician immediately if the following appear:

- signs of allergy such as: rash, itching skin often accompanied by swelling of the face, neck, lips, tongue, throat that may cause breathing difficulties/ shortness of breath, swelling of the limbs.

- signs of sensitivity to caffeine including: headache, ringing in the ears, tremor, nervousness, irritability, sleeping problems.

- restlessness, anxiety, dizziness, rapid or strong heartbeat, rapid breathing, increased frequency of urination and gastrointestinal disturbances.

- nausea, sudden loss of weight, poor appetite, yellowing of the skin and eyes, pale stool or pain in the upper abdomen.

- paracetamol can in rare cases cause the appearance of acute skin diseases that may have signs such as: redness, rash, blisters, mouth ulcers, peeling skin, extensive skin damage.

- Acute skin side effects may occur even if in the past you have taken medicines containing the active ingredient paracetamol without a problem.

- signs of changes in the blood system, such as: tendency to bleeding, unexplained hemorrhages, easier development of inflammations.

- side effects resulting from overdose (see section "If you have accidentally taken a higher dosage").

Additional side effects:

In case of prolonged use of this medicine headache, dizziness, tiredness or drowsiness may appear up to a week after stopping the treatment.

If any of the side effects gets worse, or if you suffer side effects not mentioned in the leaflet, consult your physician.

5. How to store the medicine

Avoid poisoning! This medicine, and all other medicines, must be stored in a safe place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by your physician.

Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.

Store below 25°C.
Store in the original package.

6. Additional information

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

Povidone, Guscarmlose sodium, Magnesium stearate. Coating: Hypromellose, iron oxide yellow, Titanium dioxide, Polyethylene glycol, Iron oxide red, E-110, Iron oxide black, Carmauba wax.

Each caplet contains about 1mg of Sodium.

What the medicine looks like and contents of the package:

Brown caplets with a score line on both sides.

Approved package sizes for the medicine: 10, 20, 30, 50, 100 or 1 000 caplets.

Not all package sizes may be marketed.

Marketed exclusively by: Super-Pharm (Israel) Ltd., PO Box 2171, Herzliya 4672516

Manufacturer and registration holder: DEXCEL Ltd., 1 Dexcel St., Or-Akiva 3060000, Israel

Drug registration number at the national medicines registry of the Ministry of Health: 127 94 30766 00.

This leaflet was checked and approved by the Ministry of Health in 04/2014.

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