

PARAMOL KAT CHEWABLE TABLETS

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

This medicine can be sold without a physician's prescription

Each chewable tablet contains:

Paracetamol 250 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 a physician or pharmacist.

This medicine is usually intended for children over 3 years. Under this age, refer to the physician. Use in the correct manner. Consult the pharmacist if you need additional information.

Refer to the physician if the fever lasts for more than 3 days or if the symptoms of the 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?

For pain relief and fever reduction.

Therapeutic group:

Analgesic and antipyretic.

2. Before you take the medicine:

Do not use the medicine if:

You/the child are/is hypersensitive to the active ingredient (paracetamol) or to any of the other ingredients of this medicine.

Special warnings regarding the use of this medicine:

• Before taking Paramol Kat tell the physician if:

- you or the child suffer or have suffered in the past from alcoholism or jaundice or from impaired function of the liver (including alcoholic liver disease), the kidney/urinary tract.
- you or the child are sensitive to any type of food or medicine.
- you or the child suffer from arthritis and have to take pain relievers every day.
- you are not sure about the cause of the child's disease or the disease is accompanied with rash, breathing difficulties, diarrhea or extreme tiredness or lethargy.
- Do not use this medicine frequently or for an extended period without consulting a physician.
- Avoid taking a high dosage (even if at the recommended limit) of this medicine while fasting.
- This medicine contains paracetamol that may cause damage to the liver in the following cases: when administered at a dosage higher than recommended or when administered for an extended period, when consuming alcoholic beverages during the treatment period, or when taking additional medicines that affect liver function.
- Do not take additional medicines for fever reduction and relief of pain, or cold medicines, without consulting a physician or pharmacist, in order to prevent paracetamol overdose/toxicity.
- Do not take other medicines of the "Paramol" group and/or additional paracetamol-containing medicines.

- If you or the child have developed dermal side effects in the past resulting from taking products containing paracetamol, do not take products containing paracetamol to avoid recurrence of severe skin manifestations.

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

- medicines affecting the central nervous system (e.g. sedatives, hypnotics and medicines for epilepsy),
- anticoagulants (such as: warfarin),
- medicines that increase liver enzyme activity such as barbiturates, phenytoin or carbamazepine (used mainly for epilepsy, seizures, psychiatric problems), rifampicin (an antibiotic); probenecid (for the treatment of gout); medicines for the treatment of depression such as of the tricyclic group (Tricyclic antidepressants),
- non-steroidal anti-inflammatory drugs, aspirin or other salicylates, additional pain relievers or fever reducing medicines,
- metoclopramide or domperidone (for the treatment of nausea, vomiting and other stomach problems); cholestyramine (for reduction of excess blood lipids)
- 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 a physician or pharmacist).

Use of Paramol Kat 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:

If you are pregnant or breastfeeding, consult a physician prior to use.

Use in children:

Consult a physician when using this medicine in children under 3 years of age. Parents should report to the attending physician about any side effects and any additional medicine given to the child.

3. How to use this medicine

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

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

Adults and children over 16 years of age:

2-4 tablets every 4-6 hours, up to 4 times a day.

Children: 12-16 years of age: 2-3 tablets, up to 4 times a day.

10-12 years of age: 2 tablets, up to 4 times a day.

8-10 years of age: 1½ tablets, up to 4 times a day.

4-8 years of age: 1 tablet, up to 4 times a day.

3 years of age: ½ tablet, up to 4 times a day.

Do not use this medicine more than 3 days unless instructed by the physician.

Do not exceed the dose recommended by the physician or pharmacist or the number of doses per day. Take the medicine at intervals of not less than 4 hours.

Chew the medicine before swallowing. It may be halved or crushed.

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 a physician! Even if you feel well, immediate treatment is essential because of the risk of developing severe liver damage.

Side effects may occur such as: diarrhea, poor appetite, nausea or vomiting, excessive sweating, abdominal 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 a medicine. Wear glasses if you need them.

4. Side effects:

Like all medicines, Paramol Kat can cause side effects such as dizziness, irritations in some of the users. 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 the physician immediately if the following appear:

- signs of allergy such as: rash, itching skin or hives often accompanied by swelling of the face, lips, tongue, throat that may cause swallowing difficulties or breathing difficulties /shortness of breath, or unexplained wheezing, swelling of the limbs.
- 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.
- nausea, sudden loss of weight, poor appetite and yellowing of the skin and eyes, liver or kidney damage (with prolonged use).
- side effects resulting from overdose (see section "If you have accidentally taken a higher dosage").

If any of the side effects gets worse, or if you or the child suffer from side effects not mentioned in the leaflet, you should consult a 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 of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the 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.

Storage conditions: Store below 25°C.

Store in the original package.

6. Additional information

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

Microcrystalline cellulose, Strawberry flavour, Sodium starch glycolate, Saccharin sodium, Maize starch, Fumaric acid, Ethylcellulose, Magnesium stearate, Polyethylene C-10, Silica colloidal anhydrous, Sodium laurilsulfate, Silicon dioxide, Red Lake E127.

Each tablet contains approximately 13 mg of Saccharine and approximately 2.5 mg of Sodium.

What the medicine looks like and contents of the package:

Mottled-pink tablet with a score line.

Each package contains 10, 20, 50 or 1000 tablets in blisters.

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 95 30765 00

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

Paramol Kat PIL PB0614-09