

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

The medicine is dispensed without a doctor's prescription

MACCABIMOL Caplets

Each caplet contains: Paracetamol (Acetaminophen) 500 mg

Inactive ingredients and allergens in the preparation - see section 6.

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.

This medicine is dispensed without a doctor's prescription and is intended for adults and children aged 12 years and older. Take the medicine properly. Consult a pharmacist if you need further information.

Refer to a doctor if the fever persists for more than 3 days or if the symptoms do not pass within 5 days despite use of the medicine.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for temporary relief of pain and fever of different reasons such as: headache, cold, influenza, dysmenorrhea, toothache and minor rheumatic pain.

Therapeutic group: Analgesic and antipyretic.

2. BEFORE USING THE MEDICINE

⊠ Do not use the medicine if:

- you are sensitive (allergic) to the active ingredient paracetamol (acetaminophen) or to any of the other ingredients contained in the medicine. See section 6.

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 (acetaminophen), do not take preparations containing paracetamol (acetaminophen), so that severe skin effects will not recur.
- The preparation contains paracetamol (acetaminophen), which may cause liver damage when:
 - Given at a dosage higher than recommended or for a prolonged period.
 - Consuming alcoholic beverages during the course of treatment.
 - Taking other medicines which affect liver function.
- Do not use this medicine frequently without consulting a doctor.

- Do not take other antipyretics and analgesics or cold medicines without consulting a doctor or pharmacist to prevent overdose or paracetamol (acetaminophen) poisoning.
- Do not take other medicines from the “Maccabimol family” and/or other paracetamol (acetaminophen)-containing products.
- Avoid taking a high dosage (within the recommended limit) of this medicine when fasting.
- If you are sensitive to any food or medicine, inform the doctor before taking the medicine.

Consult the doctor before commencing treatment if you are suffering, or have suffered in the past, from:

- liver disease or impaired liver function
- impaired kidney function
- alcoholism
- jaundice
- if you are pregnant or breastfeeding

⊠ 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 inform the doctor or pharmacist if you are taking medicine from the following groups or have just finished taking the medicine:

- Anticoagulants – especially warfarin.
- Medicines which stimulate production of liver enzymes (e.g., rifampicin, barbiturates).
- Antiepileptics – phenytoin, carbamazepine.
- Non-steroidal anti-inflammatory drugs.
- Metoclopramide or domperidone (for treatment of nausea, vomiting and other digestive problems).
- Chloramphenicol (antibiotic).
- Probenecid (for treatment of gout).
- Cholestyramine (to reduce excessive blood fats).

⊠ Use of the medicine and alcohol consumption

During the course of treatment with the medicine, do not consume alcohol, due to increased risk of liver damage.

⊠ Pregnancy and breastfeeding

If you are pregnant or breastfeeding, consult a doctor before commencing treatment with the medicine.

⊠ Use in children

This medicine is intended for adults and children over the age of 12 years, see section 3. Parents must report to the attending doctor about any side effects, as well as any additional medicine being given to the child.

⊠ Important information regarding some of the ingredients in the medicine

The amount of sodium in each caplet: up to 1 mg, therefore the medicine is essentially sodium-free.

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are unsure.

Recommended dosage unless otherwise instructed by the doctor:

Adults and children aged 12 years and over:

1-2 caplets every 4-6 hours, as needed.

Do not exceed a dosage of 8 caplets in any 24 hours.

Do not exceed the recommended dose.

Refer to a doctor if the fever persists for more than 3 days or if the symptoms do not pass within 5 days despite use of the medicine.

Directions for use

Do not chew or crush!

Swallow the medicine with a small amount of water.

If you took an overdose or if a child or anyone else accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you. Do not induce vomiting without explicit instruction from the doctor! Even if you feel well, immediate treatment is essential, **due to the risk of developing severe liver damage. Side effects can include nausea and vomiting, diarrhea, loss of appetite, abdominal pain, swelling, excessive sweating, pain or sensitivity in the upper abdomen and they may not reflect the severity of the liver damage.**

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 the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Maccabimol may cause side effects such as dizziness in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Severe side effects:

Stop treatment and refer to a doctor immediately:

- If severe allergic reactions occur, such as rash and itching, swelling of the face, lips, tongue, throat and/or limbs, which may cause difficulty breathing or swallowing.
- Paracetamol (acetaminophen) can, in rare cases, cause the appearance of severe skin diseases, whose signs can be: redness, rash, blisters, widespread skin damage.

Severe skin side effects may appear even if you have taken preparations containing the active ingredient paracetamol (acetaminophen) in the past with no problem.

If skin side effects appear, stop treatment and refer to the doctor immediately.

- If signs of changes in the blood system develop, such as: bleeding, bruises, development of inflammations more easily.

If a side effect occurs, if any of the side effects worsen, or if you suffer from a side effect not mentioned in this leaflet, consult the doctor immediately.

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, you can report to Perrigo via the following address:

www.perrigo-pharma.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 and the bottle. The expiry date refers to the last day of that month.
- The medicine can be used for 12 months after first opening, but not later than the expiry date.
- Store at room temperature, below 25°C.

6. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains: Corn starch, pregelatinized starch, povidone, sodium starch glycolate, hypromellose, stearic acid, polyethylene glycol, carnauba wax.
- What the medicine looks like and the contents of the package: Bottles containing 24 or 50 white caplets with “L484” debossed on one side.
- Registration holder: Perrigo Israel Agencies Ltd., 1 Rakefet St., Shoham.
- Manufacturer name: Perrigo Company, Allegan, Michigan, USA.
- Revised in December 2020.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 132-31-31121