

PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Muscol

Tablets

Each tablet contains:

Paracetamol 500 mg
Orphenadrine citrate 30 mg

For information regarding inactive ingredients, see section 2 – "Important information about some of the ingredients of the medicine" and section 6 – "Additional information".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

This medicine is not intended for use in children under 12 years of age.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended to relieve muscle pain.

Therapeutic class:

Paracetamol – analgesic and antipyretic.
Orphenadrine citrate – a skeletal muscle relaxant, which acts in the central nervous system to produce a reaction of muscle relaxation.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredients (paracetamol or orphenadrine citrate) or to any of the other ingredients this medicine contains (see section 6 – "Additional information"). Always check the ingredients to make sure you can use this medicine.
- You have glaucoma (high intra-ocular pressure).
- You have an intestinal obstruction or esophageal disease.
- You have an enlarged prostate or urinary tract obstruction.
- You have a muscle weakness disease (myasthenia gravis).

Special warnings regarding the 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 side effects will not recur.
- The preparation contains paracetamol, which may cause liver damage when:
 - Given at a higher dosage than recommended or for a prolonged period.
 - Alcoholic beverages are consumed during the course of treatment.
 - Additional medicines which affect liver function are taken.

Before commencing treatment with Muscol, inform the doctor if:

- You are sensitive (allergic) to any medicine or to any food.
 - You have heart problems.
 - You have liver or kidney problems.
 - You are suffering from alcohol addiction.
 - You have or have previously had jaundice.
 - You have any other medical condition.
 - You are taking other paracetamol-containing preparations.
 - You are taking any medicines for another medical condition.
- During treatment, you may be at risk of developing certain side effects. It is important that you understand these risks and how to monitor them. See additional information in section 4 – "Side effects".

While taking Muscol you should do the following:

- Remind any doctor, dentist and pharmacist that you visit that you are taking Muscol.
- Inform your doctor immediately if you become pregnant.
- Muscol may cause dry mouth. For temporary relief you can use sugar-free gum or candies, melt some ice in your mouth or use a saliva substitute.
- If the mouth dryness persists, refer to your dentist.

Children and adolescents

This medicine should not be given to children under 12 years of age.

Tests and follow-up

During prolonged or high-dose treatment with this medicine, blood, urine and liver function tests should be performed.

Drug interactions

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

- Sedatives and tranquilizers.
- Alcohol.
- Medicines for epilepsy – phenytoin, carbamazepine.
- Anticoagulants.
- Medicines that affect gastric emptying rate, such as metoclopramide, propantheline or domperidone, antidepressants and narcotic analgesics.
- Chloramphenicol (antibiotic).
- Non-steroidal anti-inflammatory drugs.
- Preparations that stimulate the production of enzymes in the liver (e.g. rifampicin, barbiturates).
- Cholestyramine (for lowering blood cholesterol levels).
- Probenecid (for treatment of gout).
- Flucloxacillin (an antibiotic), due to a serious risk of blood and fluid disorders (high anion gap metabolic acidosis) which require urgent treatment and may happen especially in cases of severe kidney impairment, sepsis (a condition in which bacteria and their toxins are present in the blood, leading to organ damage), malnutrition, chronic alcoholism and in cases in which the maximum daily dosage of paracetamol is used.

Certain medicines may interfere with Muscol and affect how it works, including:

- Phenothiazines, which are used to treat serious emotional and mental disorders.

- Medicines used to relieve stomach cramps or spasms.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or food supplements you are taking and whether these affect Muscol.

Using Muscol and alcohol consumption

Tell your doctor if you drink alcohol.

During treatment with Muscol, do not consume alcohol due to increased risk of liver damage. Drinking alcohol while using Muscol may cause an increase in the occurrence or severity of side effects such as drowsiness.

Pregnancy and breastfeeding

Tell your doctor if you are pregnant or planning to become pregnant and consult with him if you are breastfeeding or planning to breastfeed.

Driving and operating machinery

Care should be taken when driving or operating machinery until you know how the medicine affects you.

Muscol may cause blurry vision or drowsiness in some patients. Children should be cautioned against riding a bicycle or playing near a road etc.

Important information about some of the ingredients of the medicine

This medicine contains less than 23 mg of sodium in a tablet, and is therefore considered sodium-free.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions only.

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

The dosage and treatment regimen will be determined only by the doctor. **The generally accepted dosage is:**

Do not exceed a dosage of 2 tablets 3 times a day.

Do not exceed the recommended dose.

If pain is not relieved within 5 days despite using the medicine, refer to your doctor.

Method of use

The tablet can be halved on the score line. Swallow the medicine with some water.

The medicine may be taken with food.

There is no information regarding pulverization and chewing of the tablet.

If you accidentally took a higher dosage

If you took an overdose or if a child accidentally swallowed this medicine, refer immediately to a doctor or to the nearest hospital emergency room and take the package of the medicine with you, you may need urgent medical attention. An overdose of paracetamol-containing medicines may cause severe liver damage.

Seek treatment even if you feel okay and there is no sign of poisoning. Symptoms of an overdose include abdominal pain, nausea and vomiting, diarrhea, loss of appetite, swelling, increased sweating, pain or tenderness in the upper abdomen, and they may not reflect the severity of liver damage.

If you forgot to take the medicine

If you forgot to take this medicine at the scheduled time and remembered this within one hour of the scheduled time of the forgotten dose, take the dose as soon as you remember. If you remember at a later time, skip the forgotten dose and take the next dose at the usual time. **Do not take a double dose to compensate for a missed dose.**

Follow the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

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

If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. SIDE EFFECTS

As with any medicine, using Muscol may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Certain side effects may require medical attention.

Review the information below and if necessary, refer to the doctor or pharmacist for further questions about side effects.

Severe side effects:

Stop the treatment and refer to a doctor immediately:

- If severe allergic reactions appear, such as skin rash and itch, swelling of the extremities and/or face, lips, tongue, throat that can cause breathing or swallowing difficulties or tightness and/or wheezing in the chest.
- Paracetamol may, in rare cases, cause the appearance of severe skin diseases whose symptoms can be: redness, rash, blisters, widespread skin damage. Severe skin side effects may appear even if you had no problems in the past taking preparations containing the active ingredient paracetamol. If skin side effects appear, discontinue treatment and refer to a doctor immediately.
- If signs of changes in the blood system occur, such as unusual bruising or bleeding, persistent fatigue, developing inflammations more easily (for example, sore throat) as a result of a severe decrease in the number of white blood cells.
- Shortness of breath.
- Unusual tiredness or weakness.
- Sores, ulcers or white spots on the lips or in the mouth.
- If breathing problems appear. They are more likely to happen if you have experienced breathing problems in the past while taking other painkillers such as ibuprofen and aspirin.
- If nausea, sudden weight loss, loss of appetite and yellowing of the eyes and skin appears.

Additional side effects:

Refer to the doctor if any of the following side effects occurs:

- Fast heartbeat or palpitations
- Fainting
- Eye pain
- Hallucinations
- Breathing difficulties
- Rash
- Dry mouth (see also section 2 – "Before using the medicine")
- Abdominal or stomach cramps or pain
- Blurry vision
- Confusion
- Constipation
- Difficulty urinating
- Somnolence
- Nausea

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il>

5. HOW TO STORE THE MEDICINE?

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 an explicit instruction from the doctor.

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

Store in a dry place, below 25°C.

6. ADDITIONAL INFORMATION

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

Microcrystalline cellulose, gelatin, sodium starch glycolate, magnesium stearate, purified water, colloidal silicon dioxide, FD&C Red No. 3 aluminium lake.

What does the medicine look like and what are the contents of the package?

A light pink, round, flat tablet, with a score line on one side and debossed with the word "IKA" on the other side.

The pack contains 20 or 1,000 tablets.

Not all package sizes may be marketed.

Name and address of the marketing authorization holder and manufacturer:

Teva Israel Ltd.,

124 Dvora HaNevi'a St., Tel Aviv 6944020

The leaflet was revised in March 2024.

Registration number of the medicine in the national drug registry of the Ministry of Health:

018.08.20537