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 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 for the relief of muscle pain.
Therapeutic class:
Paracetamol – analgesic and antipyretic.
Orphenadrine citrate – a skeletal muscle relaxant, which acts in the central nervous system to produce muscle relaxation.

2. Before using the medicine

Do not use this 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").
- You have glaucoma (high intra-ocular pressure).
- You have intestinal obstruction or esophageal disease.
- You have an enlarged prostate or urinary tract obstruction.
- You have a severe muscle weakness disease (myasthenia gravis – a muscle disease that causes drooping eyelids, double vision, difficulty in speaking and swallowing and sometimes muscle weakness in the arms or legs).

Special warnings regarding the use of the medicine
- If you 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 other medicine, food, preservatives or dyes.
- You have any heart problems.
- You have liver problems.
- You have kidney problems.
- You are suffering from alcohol addiction.
- You have or have had jaundice in the past.
- You are taking other paracetamol-containing preparations.

While taking Muscol you should do the following:
- Inform all doctors, dentists and pharmacists who are treating you that you are taking Muscol.
- Inform your doctor immediately if you become pregnant while taking this medicine.
- 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 for more than two weeks, refer to your dentist.
  Continued mouth dryness can increase the risk of dental disease, including tooth decay, gum disease and fungal infections.

Children and adolescents
This medicine should not be given to children under 12 years of age.
The safety and efficacy of this medicine in children under 12 years of age have not been established.
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:
- Anticholinergics (medicines used to relieve stomach cramps or spasms).
- Antidepressants.
- Other central nervous system depressants, including alcohol. For example, antihistamines or medicines for hay fever, other medicines for allergies or colds; sedatives and tranquilizers, medicines for Parkinson's disease and narcotic analgesics (e.g. dextropropoxyphene); barbiturates, anticonvulsants; anesthetics, including some anesthetics used for dental treatments, and other muscle relaxants.
- Medicines for treatment of epilepsy or spasms (e.g., phenytoin and carbamazepine).
- Anticoagulants.
- Medicines that affect gastric emptying or medicines for treatment of nausea, vomiting and other digestion issues, e.g., metoclopramide, propantheline or domperidone.
- Chloramphenicol (antibiotic).
- Non-steroidal anti-inflammatory drugs.
- Preparations that stimulate production of enzymes in the liver (e.g. rifampicin, barbiturates).
- Cholestyramine (for lowering blood cholesterol levels).

You may be required to change the dosage of your medicines or take different medicines. Your doctor or pharmacist has more information about medicines that should be taken with caution or avoided while taking Muscol.
Using Muscol and alcohol consumption
During treatment with Muscol, do not consume alcohol due to increased risk of liver damage.
Pregnancy and breastfeeding
Muscol is not recommended for use during pregnancy or breastfeeding.
Inform your doctor if you are pregnant or breastfeeding, or if you are planning to become pregnant or to breastfeed.
Your doctor or pharmacist will talk to you about the benefit and possible risks of using Muscol during pregnancy.
If you are not sure whether to start taking this medicine or not, consult with your doctor.
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, dizziness, weakness or impaired alertness in some patients. It may also cause muscle weakness in certain patients. If you experience any of these symptoms, do not drive or operate machinery and do not engage in any activity that may be dangerous.
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. The tablet should be swallowed 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 a child accidentally swallowed this medicine, go to the doctor or the emergency room of the hospital immediately and take the package of the medicine with you. Seek treatment even if you feel okay and there are no signs of poisoning; immediate medical attention may be required.
An overdose of paracetamol-containing medicines may cause severe liver damage. Paracetamol's side effects may not reflect the severity of liver damage. Symptoms of an overdose include abdominal pain, nausea and vomiting, diarrhea, loss of appetite, swelling, increased sweating, pain or tenderness in the upper abdomen, severe drowsiness, difficulty breathing, cyanosis, excitement, confusion, severe confusion leading to coma and hallucinations, spasms, rapid heartbeat, dilated pupils and difficulty passing urine.
If you have forgotten to take the medicine
If you have forgotten to take this medicine at the scheduled time and remembered this within one hour of the forgotten dose, take a 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.**
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 <u>every time</u> you take the 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.
Severe side effects:
Stop the treatment and refer to a doctor immediately:
- If severe allergic reactions appear, such as rash and itching, swelling of the extremities and/or face, lips, tongue, throat that can cause breathing or swallowing difficulties.
- 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 bleeding, bruising, developing inflammations more easily.

Refer to the doctor if any of the following side effects occurs:
Uncommon side effects:
- Decreased urination
- Fast heartbeat or palpitations
- Fainting
- Eye pain

Rare side effects:
- Hallucinations
- Shortness of breath, breathing difficulties
- Tightness and/or wheezing in the chest
- Skin rash
- Sores, ulcers or white spots on the lips or in the mouth
- Swollen and/or painful glands
- Unusual bruising or bleeding
- Unusual tiredness or weakness

Additional side effects:
The following side effects usually do not require medical attention and may resolve in the course of the treatment as your body adjusts to the medicine.
Refer to the doctor if any of the following side effects persists or disturbs you:
Common side effects:
Dry mouth (see also section 2 – "Before using the medicine")
Uncommon or rare side effects:
- Abdominal or stomach cramps or pain
- Blurry or double vision
- Confusion
- Constipation
- Difficulty urinating
- Dizziness
- Drowsiness
- Excitement, indigestion, irritability, nausea, agitation or restlessness
- Headache
- Muscle weakness
- Unusually dilated pupils

Other side effects not listed above may also occur in some patients.
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 1000 tablets.
Not all package sizes may be marketed.
Name and address of marketing authorization holder and manufacturer:
Teva Pharmaceutical Industries Ltd., P.O. box 3190, Petah Tikva.
The leaflet was revised in May 2021 in accordance with the Ministry of Health guidelines.
Registration number of the medicine in the national drug registry of the Ministry of Health:
018.08.20537

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