

Package leaflet: Information for the patient

Muscerol 3 Film-Coated Tablets

Paracetamol 450 mg, Orphenadrine citrate 35 mg and Ibuprofen 200 mg

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Muscerol 3 is and what it is used for
2. What you need to know before you take Muscerol 3
3. How to take Muscerol 3
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1. What Muscerol 3 is and what it is used for

This medicine contains the active substances paracetamol, orphenadrine citrate and ibuprofen.

Paracetamol is an analgesic which works in a different way from ibuprofen. It is used to treat or prevent pain and reduce fever.

Orphenadrine citrate is a skeletal muscle relaxant. It acts in the central nervous system to produce muscle relaxant effects.

Ibuprofen belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs work by relieving pain, reducing inflammation, swelling and fever.

Muscerol 3 is used to treat rheumatic pain and backache. It helps relax certain muscles in your body and relieves the pain and discomfort caused by sprains, strains or other injury to your muscles and joints. Muscerol 3 is also used to treat tension headache and headaches caused by spasm of the muscles in the back of your head and neck.

This product is especially suitable for pain which requires stronger analgesia than ibuprofen or paracetamol alone.

2. What you need to know before you take Muscerol 3

Do not take Muscerol 3

- If you are allergic (hypersensitive) to paracetamol, orphenadrine citrate, ibuprofen, other NSAIDs painkillers, aspirin, or other similar medicines, or to any of the ingredients of this medicine (listed in section 6).
- If you are taking any other pain relieving products including ibuprofen, paracetamol, high dose aspirin (above 75 mg per day) or other NSAIDs including cyclo-oxygenase-2 (COX-2) specific inhibitors.
- If you have high pressure in the eye (glaucoma).
- If you are suffering from an intestinal blockage or oesophageal disease.
- If you have an enlarged prostate or bladder obstruction.
- If you have a disease of the muscles called myasthenia gravis that causes drooping eyelids, double vision, difficulty in speaking and swallowing and sometimes, muscle weakness in the arms or legs.
- If you have a tendency to bruise or bleed easily.
- If you have or have ever had an ulcer or bleeding in your stomach or duodenum (small bowel).
- If you suffer from severe heart, liver or kidney problems.
- If you are pregnant.

Warnings and precautions

Talk to your doctor or pharmacist before taking Muscerol 3:

- If you have allergies to any other medicines, foods, preservatives or dyes.
- If you are elderly.
- If you have any kidney, liver or bowel problems.
- If you have alcohol abuse problems.
- If you suffer from or you have a history of asthma.
- If you are planning to become pregnant.
- If you are breastfeeding or planning to breastfeed.
- If you have any connective tissue disorder, such as systemic lupus erythematosus (SLE).
- If you have gastrointestinal disorders or chronic inflammatory bowel disease (e.g. ulcerative colitis, Crohn's disease).
- If you have heart problems, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or you are a smoker) you should discuss your treatment with your doctor or pharmacist. Medicines such as ibuprofen may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment. There is an increased risk of the elderly having side effects.

If any of these apply to you, talk to your doctor.

Children and adolescents

Do not give this medicine to patients under the age of 18 years.

Other medicines and Muscerol 3

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including medicines obtained without a prescription.

In particular

- Anticholinergics (medicines used to relieve stomach cramps or spasms).
 - Medicines used to treat depression or other mental problems.
 - Other central nervous system (CNS) depressant drugs, including alcohol.
- Examples of CNS depressants are antihistamines or medicines for hay fever, other allergies or colds; sedatives or tranquilizers; narcotic analgesics (eg. dextropropoxyphene); barbiturates; medicines for seizures; anaesthetics including some dental anaesthetics; and other muscle relaxants.
- Medicines used to treat epilepsy or fits.
 - Medicines used to thin the blood or prevent clotting, e.g. aspirin, warfarin.
 - Medicines which affect gastric emptying e.g. metoclopramide.
 - Diuretics (drugs to remove excess fluid from the body by increasing urine output).
 - Medicines used to treat high blood pressure e.g. captopril, atenolol, valsartan.
 - Medicines used to treat high cholesterol, e.g. cholestyramine.
 - Methotrexate used to treat rheumatoid arthritis.
 - Mifepristone for pregnancy termination - ibuprofen should not be taken for 12 days after mifepristone.
 - Ciclosporin and tacrolimus which are used after transplants.
 - Corticosteroids used to treat inflammation or allergy.
 - Antibiotics, e.g. chloramphenicol or quinolone such as ciprofloxacin.
 - Sulfonylurea, such as glibenclamide for diabetes.
 - Zidovudine or ritonavir to treat a virus infection or HIV.
 - Drug such as digoxin for heart failure.
 - Pentoxifylline, used to treat problems with circulation.
 - Baclofen, used for the relief of muscle spasm.
 - Other analgesics.

You may need different amounts of your medicines, or you may need to take different medicines. Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Muscerol 3.

Muscerol 3 with food and alcohol

To reduce the likelihood of side effects, take Muscerol 3 with food. No alcohol should be consumed while taking this medicine.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

This medicine is not recommended for use during pregnancy or lactation.

Your doctor or pharmacist will discuss the possible risks and benefits of using this medicine during pregnancy.

Ibuprofen belongs to a group of medicines which may impair fertility in women. This effect is reversible on stopping the medicine. It is unlikely that ibuprofen, used occasionally, will affect your chances of becoming pregnant, however consult your doctor before taking this medicine if you have problems becoming pregnant.

Driving and using machines

Be careful driving or operating machinery until you know how the medicine affects you.

Muscerol 3 may cause some people to have blurred vision or to become drowsy, dizzy, light-headed, faint or less alert than they are normally. It may also cause muscle weakness in some people.

If you have any of these symptoms do not drive or operate machinery or do anything else that could be dangerous.

3. How to take Muscerol 3

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

The minimum effective dose should be used for the shortest time necessary to relieve symptoms.

Take 1 - 2 tablets with water and food, up to 3 times a day. Leave at least 6 hours between doses.

Do not take more than 6 tablets in any 24 hour period.

You should consult a doctor if the symptoms persist or worsen or if the product is required for more than 3 days.

If you take more Muscerol 3 than you should

If you have taken more of this medicine than you should, stop taking it and immediately contact your doctor even if you feel well. Overdose with paracetamol containing medicines can lead to liver damage. You may need urgent medical attention. You may experience symptoms of overdose which include: abdominal pain, vomiting, increased sweating, severe drowsiness, difficulty breathing, bluish color to the skin or mucus membranes that is usually due to a lack of oxygen in the blood (cyanosis), excitement, confusion, severe confusion leading to coma, convulsions, fast heart rate, dilated pupils and difficulty passing urine.

If you forget to take Muscerol 3

If you miss a dose of this medicine and remember within an hour or so of the missed dose, take it right away. If you do not remember until later, skip the missed dose and go back to taking it as you would normally. Then take the next dose at least 6 hours later. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following effects are very rare but if you experience any then stop taking this medicine immediately and contact your doctor:

- Heartburn, indigestion
 - Signs of intestinal bleeding (severe stomach pain, vomiting blood or liquid that looks like coffee granules, blood in the stools/motions, black tarry stools)
 - Signs of inflammation of the brain lining such as: stiff neck, headache, feeling or being sick, fever or feeling disoriented
 - Signs of severe allergic reaction (swelling of the face, tongue or throat, faster heart rate, dizziness or fainting)
 - Worsening of asthma and wheezing or difficulty breathing
- Adverse drug reactions previously reported with one of the individual components (ibuprofen, paracetamol and orphenadrine) may be potential undesirable effects with Muscerol 3 as well.

Ibuprofen

Uncommon: Allergic reactions such as hives, skin rashes and itching (or SLE), abdominal pain, indigestion,

heartburn and feeling sick, headache.

Rare: Diarrhea, wind, constipation and being sick

Very rare: Reduction in blood cells which can make the skin pale or yellow, cause fever, sore throat, mild mouth ulcers.

Flu-like symptoms, exhaustion or weakness, easy bruising, or bleeding from the skin or nose. High blood pressure, heart failure or chest pain. Nervousness, visual disturbance, ringing in the ears and vertigo. Liver problems:

Symptoms include yellowing of the skin or the whites of the eyes. Kidney problems: Symptoms could include

swelling of the ankles. Severe skin reactions: Symptoms could include blistering.

Medicines such as ibuprofen may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. If any of the side effects mentioned get serious, or if you notice any other side effect, STOP taking this medicine immediately and contact your doctor or pharmacist.

Paracetamol

Uncommon: the blood does not clot well, which may result in easy bruising or bleeding.

Rarely: a severe reduction in the number of white blood cells which makes infections more likely to happen; shortness of breath.

Orphenadrine

Common: dry mouth, stomach upsets, dizziness, difficulty in seeing clearly

Uncommon: rapid heart beat, changes of mood such as highly elevated mood, confusion, sleepiness, hallucinations, difficulty in sleeping, nervousness, seizure (fits), difficulty in passing water.

Rare: memory disturbance.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Muscerol 3

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the blister and the outer packaging.
 - The expiry date refers to the last day of that month.
- Do not store above 30°C. Keep away from humidity.
- Do not use this medicine if you notice visible signs of deterioration.
- Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Muscerol 3 contains

- The active substances are paracetamol, orphenadrine citrate and ibuprofen.
- Each tablet contains paracetamol 450 mg, orphenadrine citrate 35 mg and ibuprofen 200 mg.
- The other ingredients are microcrystalline cellulose, maize starch, magnesium stearate, and colloidal anhydrous silica, croscarmellose sodium, polyvinyl alcohol-polyethylene glycol copolymer, titanium dioxide, talc, povidone, stearic acid and simethicone.

What Muscerol 3 looks like and contents of the pack

White ovale plain film coated tablets.

Muscerol 3 is available in boxes containing 30 tablets.

Marketing Authorisation Holder and Manufacturer

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Reg. N° Lebanon 187181/13

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who dangled the medication.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

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Council of Arab Health Ministers
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