Package leaflet: Information for the patient

/luscerol 2 tablets

Paracetamol 450mg and Orphenadrine citrate 35mg

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

- What Muscerol 2 is and what it is used for
 What you need to know before you take Muscerol 2

3. How to take Muscerol 2

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1. What Muscerol 2 is and what it is used for

This medicine contains the active substances paracetamol and orphenadrine citrate.

Paracetamol 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. Muscerol 2 is used to treat tension headache and headaches caused by spasm of the muscles in the back

of your head and neck. It is also used to help relax certain muscles in your body and to relieve the pain and discomfort caused by sprains, strains or other injury to your muscles.

2.What you need to know before you take Muscerol 2 Do not take Muscerol 2:

- If you are allergic (hypersensitive) to paracetamol, orphenadrine citrate or other similar medicines, or to any of the ingredients of this medicine (listed in section 6).

- 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.

Warnings and precautions:

Talk to your doctor or pharmacist before taking Muscerol 2: - If you have allergies to any other medicines, foods, preservatives or dyes.

- If you have any heart problems.If you have any liver or kidney problems.If you have alcohol abuse problems.
- If you are taking other paracetamol containing products.

Children and adolescents:Do not give this medicine to a child under the age of 12 years. Safety and effectiveness in children younger than 12 years have not been established.

Other medicines and Muscerol 2: 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.

- Medicines used to treat depression.

- 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 sedatives; anaesthetics, including some dental anaesthetics; and other muscle relaxants.

- Medicines used to treat epilepsy or fits.

Medicines used to treat epilepsy or fits.
Medicines used to prevent blood clots.
Medicines which affect gastric emptying eg. metoclopramide.
Chloramphenicol which is an antibiotic.

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 2.

Muscerol 2 with drinks and alcohol:

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.

Driving and using machines:

3. How to take Muscerol 2

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

Muscerol 2 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.

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. The recommended dose in adults is two tablets three times a day.

If you take more Muscerol 2 than you should es can lead to liver damage

If you have taken more of this medicine than you should, stop taking it and immediately contact your doctor even if you feel well. 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 2 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.

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.

Talk to your doctor if any of the following side effects occur: Less common: decreased urination, eye pain, fainting, fast or pounding heartbeat.

Do not take a double dose to make up for a forgotten tablet.

Rare: hallucinations, shortness of breath, troubled breathing, tightness in chest and/or wheezing, skin rash, sores, ulcers or white spots on lips or in mouth, swollen and/or painful glands, unusual bruising or bleeding, unusual tiredness or weakness.

The following side effects usually do not need medical attention and may go away during treatment as your body adjusts to the medicine. Talk to your doctor if any of the following side effects continue or are bothersome: More common: dry mouth. Less common or rare: abdominal or stomach cramps or pain, blurred or double vision, confusion,

constipation, difficulty in urination, dizziness or light-headedness, drowsiness, excitement, indigestion,

irritability, nausea, nervousness or restlessness, headache, muscle weakness, unusually large pupils of the eyes. If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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.

- The other ingredients are microcrystalline cellulose, maize starch, magnesium stearate, colloidal

What Muscerol 2 looks like and contents of the pack

Marketing Authorisation Holder and Manufacturer

Website: www.pharmaline.com.lb

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 sold the
- medicament. - 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.

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Council of Arab Health Ministers Union of Arab Pharmacists

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5. How to store Muscerol 2 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.

6. Contents of the pack and other information What Muscerol 2 contains

The active substances are paracetamol and orphenadrine citrate. Each tablet contains paracetamol 450 mg and orphenadrine citrate 35 mg.

anhydrous silica, croscarmellose sodium, povidone, and stearic acid.

White oblong plain tablets.

Muscerol 2 is available in boxes containing 20 tablets.

Pharmaline, sal – Lebanon P.O. Box 90201 Jdeidet-El-Metn, Lebanon

Contact us: pharmaline@maliagroup.com

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