Package leaflet: Information for the patient

Muscerol Extra tablets

Paracetamol 450mg, Orphenadrine citrate 35mg and Caffeine 15mg

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
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed

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What Muscerol Extra is and what it is used for

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

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 Caffeine may help increase the effect of paracetamol on pain relief. It has been added to this medicine in a

minimal amount in order to limit potential side effects such as nervousness, irritability, sleeplessness, and occasionally rapid heartbeat. Muscerol Extra 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.

What you need to know before you take Muscerol Extra Do not take Muscerol Extra:

- If you are allergic (hypersensitive) to paracetamol, orphenadrine citrate, caffeine 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 Extra:

- If you have any liver or kidney problems. If you have alcohol abuse problems.

If you are taking other paracetamol containing products.

- If you are taking other caffeine-containing medications, food and beverages.

than 12 years have not been established. Other medicines and Muscerol Extra:

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.

- 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 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 Extra.

Muscerol Extra with drinks and alcohol:

No alcohol should be consumed while taking this medicine. Avoid too much caffeine in drinks like coffee and tea. High caffeine intake can cause difficultly sleeping, shaking and increasing heart beat.

Pregnancy and breast-feeding:

3. How to take Muscerol Extra

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: Be careful driving or operating machinery until you know how the medicine affects you. Muscerol Extra may cause some people to have blurred vision or to become drowsy, dizzy, light-headed, faint

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 or pharmacist if you are not sure. mmended dose in adults is two tablets three times a day.

If you take more Muscerol Extra than you should

Overdose with paracetamol containing medicines can lead to liver damage. If you have taken more of this medicine than you should, stop taking it and immediately contact your doctor

or less alert than they are normally. It may also cause muscle weakness in some people.

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 Extra 🖥 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.

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

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 If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed

5. How to store Muscerol Extra - 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 Extra contains

The active substances are paracetamol, orphenadrine citrate and caffeine. Each tablet contains paracetamol 450 mg, orphenadrine citrate 35 mg and caffeine 15 mg. The other ingredients are microcrystalline cellulose, maize starch, magnesium stearate, colloidal anhydrous

silica, croscarmellose sodium, povidone, and stearic acid. What Muscerol Extra looks like and contents of the pack White oblong plain tablets. Muscerol Extra is available in boxes containing 20 tablets.

Marketing Authorisation Holder and Manufacturer

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Reg. No Lebanon 194752/04

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.

This is a medicament

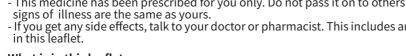
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- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

- 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. - Keep all medicaments out of reach of children.

Council of Arab Health Ministers

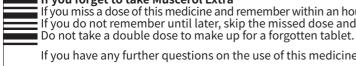


- If you have allergies to any other medicines, foods, preservatives or dyes. - If you have any heart problems.

Children and adolescents:

Do not give this medicine to a child under the age of 12 years. Safety and effectiveness in children younger







bothersome:

