

MYOFLEX TABLET

Orphenadrine/Paracetamol (35mg /450mg)

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What *Myoflex* is used for

It is used for the relief of muscle spasm associated with acute painful conditions of muscle and bone.

How *Myoflex* works

Orphenadrine citrate reduces muscle spasm. It has pain relieving activity and muscle relaxant properties. Paracetamol has pain relieving and fever reducing properties.

Before you use *Myoflex*

- When you must not use it

- Do not take *Myoflex* if allergic to orphenadrine, paracetamol or to other ingredients in it.
 - Do not take *Myoflex* if there is achalasia (swallowing disorder), bladder neck obstruction, glaucoma (high pressure of the eyes), myasthenia gravis (autoimmune disorder), enlargement of the prostate, or stomach-intestinal obstruction.
- Allergy alert: Paracetamol may cause severe skin reactions. Symptoms may include skin reddening, blisters or rash. These may be signs of a serious condition. If these reactions occur, stop use and seek medical assistance right away.

- Before you start to use it

- Inform the doctor or pharmacist if you have heart problems, irregular or increased heartbeats, central nervous system depression, liver or kidney function impairment and urine retention.

Pregnancy and breastfeeding

Safety for use in pregnancy and breast feeding has not been established.

- Taking other medicines

- Inform your doctor or pharmacist if taking:
- any medicines used for depression
 - antimuscarinics (atropine for diarrhea)
 - medicines that affect the liver

How to use *Myoflex*

- How much to use

Adults: oral, 1 – 2 tablets three times a day. Children: Dosage has not been established. Follow all directions given by your doctor

and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

Use as directed by the doctor or pharmacist.

- How long to use it

Continue taking *Myoflex* for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it. Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Clinical features include diarrhoea, loss of appetite, increased swelling, nausea or vomiting, stomach or abdominal cramps, liver problems, coma, metabolic acidosis (improper chemical balance of blood), kidney problems, irregular heartbeats or heart failure.

While you are using *Myoflex*

- Things you must do

Take your medicine exactly as your doctor has told you. Tell the doctor, dentist and pharmacist treating you that you are taking *Myoflex*. Tell the doctor immediately if you are pregnant while taking this medicine.

- Things you must not do

This preparation contains paracetamol. Do not take any other paracetamol containing medicines at the same time. Do not stop taking the medicine unless advised by your doctor. Do not take any new medicines without consulting your doctor or pharmacist. Do not give *Myoflex* to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Careful when driving or doing jobs that require alertness due to risk of drowsiness.

Side effects

Myoflex can cause side effects, although not everybody gets them. Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Blurred vision, dry mouth, nausea, vomiting, vertigo, skin rash, headache, dizziness, drowsiness, constipation, increased pressure in the eye, confusion, excitement, difficulty in urinating and stomach intestinal pain may occur. Skin hypersensitivity reactions like skin rashes, swelling beneath the skin, severe skin reactions such as Stevens Johnson Syndrome/Toxic Epidermal Necrolysis have been reported.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety)

Storage and Disposal of *Myoflex*

- Storage

Store in a cool, dry place, below 30°C. Protect from light. Keep out of reach and sight of children.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

Product description

- What it looks like

Blue, oval, biconvex and top-scored tablet.

- Ingredients

- Active ingredients: orphenadrine citrate and paracetamol
- Inactive ingredients: cornstarch, indigo carmine lake, polyvinylpyrrolidone, magnesium stearate, microcrystalline cellulose

- MAL number:

MAL19930136AZ

Manufacturer and Product Registration Holder

Prime Pharmaceutical Sdn. Bhd.
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