

MYOXERIL[®] 10MG

Cyclobenzaprine hydrochloride

Film-coated tablets

Composition:

Each film-coated tablet contains:

Cyclobenzaprine hydrochloride.....10mg

List of excipients:

Microcrystalline cellulose, Lactose, Cornstarch, Croscarmellose sodium, colloidal anhydrous silica, Magnesium stearate, Instacoat, Yellow iron oxide

Indications:

MYOXERIL[®] is indicated for the treatment of muscle spasms associated with acute, non-central musculoskeletal pain.

MYOXERIL[®] reduces muscle spasm and associated signs, such as pain, motor limitations, and restrictions in activities of daily living.

Posology and method of administration::

The recommended dose is one 10 mg tablet, three times a day.

The dose can range between 20 mg and 40 mg a day, in fractioned doses (2-4 tablets a day), up to a maximum dose of 60 mg a day (6 tablets a day).

The duration of treatment should not exceed 3 weeks.

Pharmacological properties:

MYOXERIL[®] is a medication that contains the active ingredient cyclobenzaprine. This is a muscle relaxant that works on the musculoskeletal system.

MYOXERIL[®] relieves skeletal muscle spasm of local origin without interfering with muscle function. It is ineffective in muscle spasm due to central nervous system lesions.

MYOXERIL[®] has a potent peripheral and central anticholinergic effect.

Pharmacokinetic properties:

Cyclobenzaprine hydrochloride is well absorbed in humans after oral administration, but plasma levels vary widely between one individual and another. Between 38% and 51% is excreted in the urine, and between 14% and 15% in feces. Oral absorption is almost complete. The half-life ranges from 1 to 3 days.

Cyclobenzaprine hydrochloride is extensively metabolized in humans. Oxidative N-demethylation, one of the metabolic pathways of cyclobenzaprine, is mediated by CYP3A4 and CYP1A2, and to a lesser extent, CYP2D6. Cyclobenzaprine is eliminated quite slowly, with an effective half-life of 18 hours (range of 8 to 37 hours; n = 18); plasma clearance is 0.7 L/min.

Plasma concentrations of cyclobenzaprine are generally higher in the elderly and in patients with hepatic impairment.

Side effects:

Like all medications, cyclobenzaprine can cause undesirable effects, but they do not occur systematically in everyone.

The most common effects are sleepiness, dry mouth, and dizziness.

Other undesirable effects described for cyclobenzaprine are:

- Immune system disorders: allergic reactions consisting of skin rash, urticaria, swelling of the face and tongue.
- Psychiatric disorders: confusion, nervousness, depression, sleeping problems, anxiety, agitation, abnormal thoughts, hallucinations, insomnia, disorientation, excitation, euphoria.
- Nervous system disorders: trembling, loss of motor coordination, disrupted speech, tingling, numbness, seizures, hypertonia (increased muscle tone or stiffness), dizziness.
- Eye disorders: blurred vision.
- Ear and labyrinth disorders: tinnitus.
- Heart and vascular disorders: tachycardia, syncope, arrhythmias, hypotension, palpitations, vasodilation.
- Gastrointestinal disorders: bad taste in the mouth, constipation, dyspepsia (poor digestion), nausea, vomiting, diarrhea, gastritis, anorexia, changes in taste, flatulence, abdominal pains, thirst, gastrointestinal pain.
- Hepatobiliary disorders: abnormal liver function, hepatitis, jaundice and cholestasis (blocking of the flow of bile).
- Musculoskeletal and connective tissue disorders: muscle contractions and local weakness.
- Kidney and urinary disorders: increased frequency of urination and/or urinary retention, reduced bladder tone.
- General problems: weakness, headache, asthenia (loss of strength), discomfort
- Endocrinal disorders: hypoglycemia
- Skin and subcutaneous tissue problems: sweating

Contraindications:

Do not take MYOXERIL®:

- If you are allergic to cyclobenzaprine or any of the ingredients of this medication.
- If you have heart problems, such as arrhythmia, cardiac conduction abnormalities, congestive heart failure, or recent myocardial infarction.
- If you have a thyroid disease called hyperthyroidism (overactive thyroid).
- If you take or you have taken MAOIs (medications for depression or Parkinson's disease) within 14 days before starting treatment with MYOXERIL®.

Interaction with other medicinal products and other forms of interaction:

Tell your doctor or pharmacist if you are using, or if you have recently used, or if you might use any other medication, even one that can be obtained without a prescription.

During treatment with MYOXERIL®, avoid taking the following medications, unless indicated by your doctor:

- Anti-Parkinson's medications (MAOIs: rasagiline, selegiline), antidepressants (MAOIs: tranylcypromine, moclobemide), painkillers (tramadol); antibacterial drugs (linezolid), because they might cause raised blood pressure or serious convulsions if they are taken with cyclobenzaprine.
- Medications that might cause tachycardia or arrhythmias if they are taken with cyclobenzaprine:
 - Medications used for heart problems such as antiarrhythmics (dronedronone, Amiodarone, Disopyramide, Flecainide, Ranolazine), anti-angina medications (Ivabradine) and beta-blockers (sotalol);

- Anti-cancer drugs (medications used in the treatment of cancer: arsenic trioxide, lapatinib, nilotinib, pazopanib, sunitinib, vemurafenib, and vinflunine)
 - Antibiotics (clarithromycin, erythromycin, telithromycin, levofloxacin, moxifloxacin).
 - Antifungals (fluconazole, voriconazole).
 - Antimalarials (lumefantrine).
 - Antipsychotics (medications for treating schizophrenia: pimozide, asenapine, clozapine, droperidol, paliperidone, ziprasidone).
 - Antidepressants (fluoxetine).
 - Medications that act on the nervous system (methadone, tetrabenazine, pasireotide).
 - Medications containing sodium phosphate.
 - Anti-asthmatics (formoterol).
- Other anticancer drugs (procarbazine); anti-migraine and antidepressants (duloxetine, hydroxytryptophane, trazodone, desvenlafaxine, escitalopram)
 - Medications for treating arterial hypertension (guanethidine)
 - Alcohol and other medications that slow down the activity of the nervous system.

Special warnings and Precautions for use:

Consult your doctor, your pharmacist, or your nurse before starting to take MYOXERIL®:

- If you are taking other central nervous system depressants.
- If you have a history of urinary retention.
- If you have raised intraocular pressure or closed-angle glaucoma.
- If you have epilepsy.
- If you have liver problems.
- If you have hypertension.
- If you are an elderly person.

Pregnancy and lactation:

If you are pregnant or you are breastfeeding, if you think you are pregnant, or if you plan to become pregnant, ask your doctor or pharmacist before using MYOXERIL®.

Pregnancy: It is not known if cyclobenzaprine is harmless during pregnancy. If you are pregnant, your doctor will only prescribe you this medication if he/she considers that the advantages of the treatment are greater than the potential risks for you and your child.

Breastfeeding: It is not known if cyclobenzaprine passes into breast milk. If you take this medication while breastfeeding, your doctor will have to monitor and evaluate the potential risk of breastfeeding for the child compared to the benefit of the treatment for the woman.

Driving vehicles and using machines:

MYOXERIL® can cause sleepiness, vertigo, vision problems, clumsiness, or instability in some people. If that occurs, do not drive and do not use dangerous tools or machines.

Storage precautions:

Store MYOXERIL® in a dry place, protected from light, at a temperature below 30°C.

Nature and contents of container:

MYOXERIL® is supplied in the form of yellow film-coated tablets. The tablets are packed in aluminum/aluminum blister packs of 10 in boxes containing 20 tablets.

Medication supplied under medical prescription.

Keep out of the sight and reach of children.

Marketing authorization holder:

CROSS PHARM S.A.

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Switzerland

Manufactured by:

The Madras Pharmaceuticals

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Mfg. Lic. No.: 247