Mydocalm® tablets

Registration number:
R N002409/01

Trade name:
Mydocalm®

International non-proprietary name (INN):
Tolperisone

Chemical name:
2-methyl-1-(4-methylphenyl)-3-(1-piperidinyl)-1-propanone hydrochloride

Dosage form:
Film-coated tablets

Composition:
Active ingredient: Tolperisone hydrochloride 50 mg or 150 mg per tablet
Excipients:
Citric acid monohydrate 0.730 mg and 2.190 mg
Colloidal silicon dioxide 0.800 mg and 2.400 mg
Stearic acid 1.700 mg and 5.100 mg
Talc 4.500 mg and 13.500 mg
Microcrystalline cellulose 14.000 mg and 42.000 mg
Corn starch 29.770 mg and 89.310 mg
Lactose monohydrate 48.500 mg and 145.500 mg
Film coating composition:
Colloidal silicon dioxide 0.045 mg and 0.089 mg
Titanium dioxide (Color Index 77891, E171) 0.244 mg and 0.487 mg
Lactose monohydrate 0.392 mg and 0.785 mg
Macrogol 6000 0.392 mg and 0.785 mg
Hypromellose 3.927 mg and 7.854 mg

Description:
50 mg Tablets: White or almost white, round, biconvex, film-coated tablets with a faint characteristic odor and "50" engraved on one side. Tablets appear white or almost white when broken.
150 mg Tablets: White or almost white, round, biconvex, film-coated tablets with a faint characteristic odor and "150" engraved on one side. Tablets appear white or almost white when broken.

Pharmacological group:
Central muscle relaxant

ATC code:
M03BX04

Pharmacological properties:

Pharmacodynamics:
A centrally acting muscle relaxant. The exact mechanism of action is not fully understood. Mydocalm has membrane-stabilizing and local anesthetic effects. It inhibits impulse conduction in primary afferent fibers and motor neurons, leading to the blockade of spinal mono- and polysynaptic reflexes. Additionally, it likely reduces mediator release by inhibiting calcium influx into synapses. In the brainstem, it reduces excitation conduction along the reticulospinal pathway. Independently of the central nervous system, it improves peripheral blood flow, which is partially attributed to its mild antispasmodic and adrenergic blocking effects.

Pharmacokinetics:
After oral administration, tolperisone is well absorbed from the gastrointestinal tract. Peak plasma concentration is achieved within 0.5-1 hour, with a bioavailability of approximately 20%.
Tolperisone is metabolized in the liver and kidneys and is excreted in urine as metabolites (over 99%). The pharmacological activity of these metabolites is unknown.

Indications:
- Treatment of pathologically increased muscle tone and spasms of striated muscles due to organic diseases of the central nervous system (e.g., pyramidal tract lesions, multiple sclerosis, stroke, myelopathy, encephalomyelitis).

- Treatment of increased muscle tone, spasms, and contractures accompanying locomotor system diseases (e.g., spondylosis, spondyloarthrosis, cervical and lumbar syndromes, large joint arthroses).
- Postoperative recovery in orthopedics and traumatology.
- As part of combination therapy for obliterating vascular diseases (e.g., obliterating atherosclerosis, diabetic angiopathy, obliterating thromboangiitis, Raynaud's disease, diffuse scleroderma).
- Diseases caused by vascular innervation disorders (e.g., acrocyanosis, intermittent angioneurotic dysbasia).
- Little's disease (infantile cerebral palsy) and other encephalopathies with muscle dystonia.

Contraindications:

- Hypersensitivity to any components of the medication
- Myasthenia
- Children under 3 years of age
- Use during pregnancy and lactation is not recommended due to insufficient safety data.

Dosage and administration:

Adults and children aged 14 years and above: Initially, 50 mg 2-3 times daily, gradually increasing to 150 mg 2-3 times daily.

Children:

Age Group	Dose (mg/kg body weight daily)	Number of Doses per Day
Aged 3-6 years	5 mg/kg	3
Aged 7-14 years	2-4 mg/kg	3

Tablets should be taken orally after meals, without chewing, with a small amount of water.

Side effects:

Muscle weakness, headache, hypotension, nausea, vomiting, abdominal discomfort (usually resolves with dose reduction).
Rare allergic reactions: itching, erythema, urticaria, angioedema, anaphylactic shock, bronchospasm.

Overdose:

No reported cases of overdose. No specific antidote is available. In case of overdose, gastric lavage and symptomatic therapy are recommended.

Drug interactions:

No significant interactions limiting the use of Mydocalm have been reported.
Despite its central nervous system action, tolperisone does not cause sedation and can be used with sedatives, hypnotics, and alcohol-containing products. It enhances the effect of niflumic acid, potentially requiring a dose reduction of the latter.

Special instructions:

Use strictly as prescribed to avoid complications. No data suggests an effect on the ability to drive or operate machinery.

Form of release:

Film-coated tablets: 50 mg and 150 mg. Packaged in PVC/Al blisters, 10 tablets per blister, with 3 blisters in a carton with instructions.

Storage conditions:

Store in a dry place at 15-30°C. Keep out of reach of children!

Shelf life:

3 years. Do not use beyond the expiration date indicated on the packaging.

Dispensing conditions:

Prescription only

Manufacturer:

Gedeon Richter Plc. 1103 Budapest, Demrei Street 19-21, Hungary.

These instructions translated from official manufacturer instructions in Russian by Extrapharma online pharmacy