Package leaflet: information for the user

MYOTOP®-450 SR

(Tolperisone Hydrochloride Prolonged-release Tablets 450 mg)

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:

1. What MYOTOP®-450 SR is and what it is used for
2. What you need to know before you take MYOTOP®-450 SR
3. How to take MYOTOP®-450 SR
4. Possible side effects
5. How to store MYOTOP®-450 SR
6. Contents of the pack and other Information

1. What is MYOTOP®-450 SR and what it is used for

MYOTOP®-450 SR tablet contains Tolperisone as an active ingredient. Tolperisone is a medicine that acts on the central nervous system (brain and spinal cord). It is used to treat the pathological (disease-induced) increased skeletal muscle tone in adults. It provides relief from the discomfort associated with acute, painful musculoskeletal conditions such as rigidity, tension, stiffness, and skeletal muscle spasms.

2. What you need to know before you take MYOTOP®-450 SR

Do not take MYOTOP®-450 SR if you:

- If your allergic to the active substance or to any of the other ingredients of this medicine.
- You suffer from myasthenia gravis (an autoimmune disease characterized by muscle weakness)
- You are Pregnant or breastfeeding.

When should you be extra careful with this medicine?
Hypersensitivity reactions

During post-marketing experience with medicinal products containing tolperisone (the active substance of this medicinal product) hypersensitivity reactions were reported. Hypersensitivity reactions ranged from mild skin reactions to severe systemic reactions.
Women, elderly patients, or patients treated concomitantly with other drugs mainly NSAIDs (group of painkillers with a strong anti-inflammatory effect)) appear to be at a higher risk of hypersensitivity reactions. Also, patients with a drug allergy or allergic diseases or conditions (such as atopy: hay fever, asthma, atopic dermatitis with high serum IgE, hives) in the past or patients who simultaneously suffer from viral infections appear to be at greater risk of an allergic reaction to this medicine.

Early indications of hypersensitivity include: flushing, rash, severely itchy skin (with bumps), wheezing, difficulty breathing with or without swelling of the face, lips, tongue and/or throat, difficulty swallowing, fast heart rate, low blood pressure, rapid drop in blood pressure.
If you feel these symptoms, stop taking this medicine immediately and contact your doctor or the nearest emergency department.
If you have ever had an allergic reaction to tolperisone, you should not use this medicine.
If you have a known allergy to lidocaine, you are more likely to be allergic to tolperisone. In this case, talk to your doctor before starting treatment.
Do not take the drug again if a hypersensitivity reaction occurs.

Other medicines and MYOTOP®-450 SR.
If you are taking, or have you recently taken, any other medicines besides Tolperisone or the possibility that you will take other medicines in the near future? Please tell your doctor or pharmacist.

There are no data available on the dose-limiting interaction of this drug. Although tolperisone is a centrally acting agent, it does not cause sedation (it does not reduce your ability to concentrate). Therefore, it can be used at the same time as tranquilizers and sleeping pills. In case of co-administration with other centrally acting muscle relaxants, a dose adjustment of tolperisone should be considered.
Tolperisone enhances the effect of niflumic acid. Therefore, a dose reduction of niflumic acid or other nonsteroidal anti-inflammatory drugs (NSAID) should be considered in case of co-administration.

When taking MYOTOP®-450 SR with food and drink?

The consumption of food and drink does not affect the absorption of this medicine. It is important that you take the medicine after having eaten enough (after a meal).

Pregnancy and breastfeeding
Are you pregnant, do you think you are pregnant, do you want to become pregnant or are you breastfeeding? Please contact your doctor or pharmacist before using this medicine. Tell your doctor if you are pregnant or planning to become pregnant. Because there is no evidence that this drug could have a harmful effect on the fetus, your doctor should decide whether you

should take this medicine after careful consideration of the benefit-risk balance, especially in the first three months of pregnancy.
This medicine should not be used during breastfeeding.

Driving and using machines
The medicine does not affect the ability to drive or use machines. However, if you experience dizziness, drowsiness, disturbance in attention, epilepsy, blurred vision or muscle weakness while taking this medicine, consult your doctor.

How to take MYOTOP®-450 SR.
Always take this medicine exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Please contact your doctor or pharmacist.
The recommended dose is: 1 MYOTOP®-450 SR tablet once a day.
Take this medicine after meals with a glass of water.
Tablet should be swallowed whole & not to be broken, crushed or chewed.

Use in children: not recommended in children due to lack of data.

Patients with renal impairment
Your normal medical check-ups will include regular assessment of your renal function and general condition during treatment with this medicine, as an increase in side effects has been observed in this patient group. You should not take this medicine if you have severe kidney problems.
Patients with hepatic impairment
Your liver function and general condition will be regularly assessed during your normal medical check-ups during treatment with this medicine as an increase in side effects has been observed in this patient group. You should not take this medicine if you have severe liver problems.
Have you taken too much of this medicine?

Symptoms of overdose may include drowsiness, gastrointestinal symptoms (such as nausea, vomiting, upper abdominal pain), fast heart rate, high blood pressure, slow movement, and dizziness. In severe cases, seizures, slowing or cessation of breathing and coma have been reported.
If you take more of this medicine than prescribed by your doctor, contact your doctor or pharmacist immediately or go to the emergency department of your nearest hospital.

If you forget to take this medicine?
Do not take a double dose to make up for a forgotten tablet.

If you stop taking this medicine.

Do not stop taking the drug prematurely, even if you experience the effect of this drug as too strong or too weak. In that case, contact your doctor or pharmacist. Do you have any other questions about the use of this medicine? Please contact your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone gets them. Most side effects are usually mild and disappear after treatment is stopped.
Uncommon: occur in less than 1 in 100 patients.
Rare: occur in less than 1 in 1000 patients
Very rare: occurs in less than 1 in 10,000 patients (including individual cases).

Uncommon side effects: loss of appetite, insomnia, sleep disorders, headache, dizziness, drowsiness, low blood pressure, abdominal pain, diarrhea, dry mouth, indigestion, nausea, muscle weakness, muscle pain, pain in arms and legs, weakness, malaise (generally feeling unwell, feeling sick), fatigue.

Rare side effects: hypersensitivity reaction (allergic reaction), severe allergic reaction, decreased activity, depression, disturbance in attention, trembling hands, attack of unconsciousness with muscle twitching (convulsion), loss of sensation, sensory disturbance, lethargy, visual disturbance, vertigo, ringing in the ears, tightness in the chest, fast heartbeat, palpitations, reduced blood pressure (hypotension), flushing, shortness of breath, nosebleed, panting, pain in the stomach area, constipation, flatulence, vomiting, mild liver damage, allergic skin symptoms, increased perspiration, itch (pruritus), hives (urticaria: rash with intense itching and bumps), rash, urinary incontinence (inability to hold urine), proteins in the urine, discomfort in arms and legs, feeling of drunkenness, feeling of heat, thirst, irritability, increase in bilirubin level (is a waste product that is mainly release during the breakdown of old red blood cells) , abnormal levels of liver enzymes, decreased platelet count, increase in white blood cell count.
Very rare side effects: anemia, swollen lymph nodes, very severe allergic reaction, abnormal feeling of thirst (polydipsia), confusion, slow heart rate, osteoporosis, chest pain, increase in creatinine level.

Reporting side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly: Website: **www.zuventus.co.in** and click the tab “Safety Reporting” located on the top of the home page.

By reporting side effects, you can help provide more information on the safety of this medicine.

You can also report the side effect with the help of your treating physician.

5. How to store MYOTOP®-450 SR.

Store in the original packaging.

Store protected from light & moisture at a temperature not exceeding 25°C. Keep out of reach of children

Do not use Tolperisone after the expiry date. which is stated on the carton after 'EXP'. There is a month and a year. The last day of that month is the expiration date.
Do not flush medicines down the sink or toilet or throw them in the rubbish bin. Ask your pharmacist what to do with medicines you no longer use. They are then destroyed in a responsible manner and do not end up in the environment.

6. Contents of The Pack and Other Information

What MYOTOP®-450 SR contains

This prolonged-release tablet contains tolperisone hydrochloride 450 mg as an active ingredient.

Pack sizes: 5 Blister strips of 6 tablets in each strip

Marketing Authorisation Holder

Zuventus Heathcare Ltd.

Kamerey Bhasmay, Elaka Pakyong,

Rangpo, East-Sikkim 737 132.

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