

Patient Information Leaflet

MYOTOP[®]-D

Tolperisone Hydrochloride & Diclofenac Sodium Tablets (150 mg + 50 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

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

1. What MYOTOP[®]-D is and what it is used for

MYOTOP[®]-D is a fixed dose tablet of a Tolperisone 150mg (skeletal muscle relaxant) and Diclofenac 50mg (pain killer).

Tolperisone is a muscle relaxant. It works on the centers in the brain and spinal cord to relieve muscle stiffness or spasm and to relieve pain and improve the movement of muscles. Diclofenac is a non-steroidal anti-inflammatory drug (NSAID) which works by blocking the release of certain chemical messengers that cause pain and inflammation (redness and swelling).

MYOTOP[®]-D is used for the treatment of musculoskeletal spasm and pain like strain, sprain, rigidity in adult. It improves the movement of muscles and provides relief from pain and discomfort associated with muscle spasms.

2. What you need to know before you take MYOTOP[®]-D

Do not take MYOTOP[®]-D:

- If you are allergic to any of the ingredients of this medicine.
- If you are suffering from a disease called myasthenia gravis
- If you are pregnant or lactating woman

- If you have stomach ulcer.
- If you have Liver or kidney failure
- If you have heart failure, heart disease, peripheral arterial disease.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking MYOTOP®-D.

Take special care with **MYOTOP®-D**

Tell your doctor before you take this medicine if you:

- If you have advanced renal disease
- If you have peptic ulcer disease, gastrointestinal perforation or bleeding
- If you have impaired renal or liver functions
- If you have blood dyscrasias
- If you have hypersensitivity to aspirin or other NSAIDs
- If you are chronically treated with NSAIDs
- If you are using other muscle relaxants

Tell your doctor immediately if during treatment you suffer from

hypersensitivity reactions (pruritis, erythema, exanthema, dyspnea, angioneurotic edema)

Other medicines and MYOTOP®-D

Tell your doctor if you are taking or have taken the following medications.

- Aspirin
- Immune-system suppressant: methotrexate, cyclosporine
- Medicines used to treat heart failure: digoxin
- Medicines used to treat high blood pressure- ACE inhibitors, diuretics
- Medicine used to treat mania: lithium
- Medicines that stop blood clotting, such as warfarin
- Neuromuscular blocking agents

Pregnancy, breast-feeding and fertility

You should not take MYOTOP®-D when you are pregnant.

You should not breast-feed when taking MYOTOP®-D.

Driving and using machines

Undesirable effects such as dizziness, drowsiness, fatigue and visual disturbances are possible. If affected, you should not drive or operate machinery.

3. How to take MYOTOP®-D

Adults

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

In adults, the recommended dose is one tablet of MYOTOP[®]-D three times daily. Swallow the tablet whole with some water.

Use in children and adolescents

MYOTOP[®]-D is not used to treat children and adolescents.

If you take more MYOTOP[®]-D than you should

Tell your doctor or emergency department in hospital immediately.

If you forget to take MYOTOP[®]-D

Take the forgotten tablet as soon as you remember. Take the next tablet 24 hours after this and continue taking your tablets every 24 hours. Do not take a double dose to make up for a forgotten tablet.

If you stop taking MYOTOP[®]-D

Unless your doctor instructs you to stop treatment, it is important to continue taking MYOTOP[®]-D. If you stop and your original symptoms come back tell your doctor or pharmacist immediately.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Tell your doctor, nurse or pharmacist immediately if you notice any of these side effects during your treatment with MYOTOP[®]-D:

Most common side effects include

- Gastrointestinal (GI) upset with abdominal pain
- Heartburn
- Nausea, vomiting
- Diarrhea
- Dyspepsia (persistent or recurrent pain or discomfort in the upper abdomen)
- Flatulence (passing gas)
- GI ulcers
- Bleeding / perforation and dryness of mouth

Other side effects include:

- Changes in some blood test results including those measuring your kidney and liver
- Abnormal renal function
- Edema
- Anemia (low red blood cell)
- Headaches
- Fatigue
- Muscle weakness or transient physical asthenia

- Dizziness
- Increased bleeding time
- Pruritus (Itching), rashes
- Arterial hypotension
- Hypersensitivity and other skin allergic reactions like skin rash, hives

Reporting of 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 right end 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[®]-D

Keep this medicine out of the sight and reach of children.

Store in a cool and dry place.

Protected from light.

6. Contents of the pack and other information

What MYOTOP[®]-D contains

- MYOTOP[®]-D is a fixed dose combination of a Tolperisone 150 mg (skeletal muscle relaxant) and Diclofenac 50mg (pain killer).

Pack size: 10 Blister strips of 10 tablets each

Marketing Authorisation Holder

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