

PACKAGE LEAFLET: INFORMATION FOR THE USER

MUSCOFLEX

8 mg, capsule, hard

THIocolchicoside

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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?

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1. WHAT MUSCOFLEX IS AND WHAT IT IS USED FOR

The primary effect of Muscoflex is characterized by a muscle relaxation. Muscoflex 8 mg capsule is used for the symptomatic treatment of painful muscle spasms.

2. BEFORE YOU TAKE MUSCOFLEX

You do not need to take / use Muscoflex capsules 8 mg if

- If the muscles do not work (there is no possibility of contraction)
- If there is a hypersensitivity to thiocolchicoside (muscle relaxation) or any of its excipients.
- Pregnancy and breastfeeding.

Thiocolchicoside is not recommended for children.

Precautions during use of Muscoflex 8 mg hard capsules

- If you are epileptic or have a risk of seizures
- If you have diarrhea during the administration of this product

- If any of these signs occur or have occurred in the past, talk to your doctor.

Taking Muscoflex hard capsules of 8 mg with food and drink

Muscoflex does not show any interaction with food and drink.

Important information about some of the ingredients that are found in the Muscoflex

Muscoflex contains lactose monohydrate as a secondary substance. If you are told that you have any kind of intolerance to sugars you must contact your doctor before using this medicine.

Pregnancy and breastfeeding

Muscoflex is contraindicated in pregnancy.

Administration of medicine in women who are at the possibility of conception / contraception:

Women who have possibility of conception should use effective contraception during treatment.

The period of pregnancy: During the studies conducted on animals, toxicity to fertility was observed. No clinical data is insufficient to assess the safety of use of the medicine during pregnancy. Therefore, the potential damage that could occur in the embryo or fetus is not known. So, there are no contraindications for the use of thiocolchicoside during pregnancy.

The period of breastfeeding: given that the thiocolchicoside is secreted into milk, Muscoflex should not be used during breastfeeding.

If you are breastfeeding, you should not take Muscoflex 8 mg hard capsules.

Driving and using machines:

There are no data available regarding the impact of the medicine on the ability to drive and use machines. Clinical studies have shown that thiocolchicoside does not have any impact on psychomotor skills. However, there have been rare cases of drowsiness, you should be cautious while driving or using machines.

Taking other medicines:

Co-administration with other medicines that show the relaxing effect on the muscles is not recommended, because they can increase the impact of each other. For the same reasons, if it is used together with other medicines that have an effect on the smooth muscles, you should be alert to the possibility of frequent side effects, and the patient should be monitored.

3. HOW TO TAKE MUSCOFLEX

One capsule (thiocolchicoside 8 mg) twice a day, a maximum of 2 capsules a day (16 mg thiocolchicoside) after meals.

The period of treatment lasts from 5 to 7 days.

Frequency and duration of therapy

Muscoflex is intended for oral use. Do not chew the capsules.

Take the capsule with water (eg. One glass of water)

If the doctor has not prescribed otherwise, follow these instructions.

Do not forget to take medication on time.

Your doctor will refer you to the time of treatment with Muscoflex. Do not interrupt the period of treatment earlier if you do not want to interrupt the results.

Always follow your doctor's instructions. There are individual differences for each individual.

Before you change or stop the treatment inform your doctor.

If you take more Muscoflex 8 mg capsules than you should

Talk to your doctor, emergency room, or pharmacist if you have taken more Muscoflex tablets than specified in this leaflet or more than your doctor has prescribed.

If you forget to take Muscoflex 8 mg capsule

If you forget to take Muscoflex you don't need to worry, take one capsule as soon as you remember and then continue taking it as before.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Muscoflex hard capsules can cause side effects.

As with all medications, Muscoflex can have effects on people who are hypersensitive to the components of the Muscoflex.

If you notice any of the following occurrences, stop taking Muscoflex immediately and call your doctor or call the nearest emergency room or hospital:

- Swelling of the arms, legs, ankles, face, lips, or mouth, throat so that it causes difficulties in breathing or swallowing.
- Itching, swelling of the mucous membranes (angioneurotic edema)
- fainting (vasovagal syncope)
- a rash on the skin

All the above listed the side effects are very serious. If you notice any of them, it means that you are allergic to Muscoflex. These serious side effects are very rare.

If you notice some of the following, inform your doctor immediately or contact the nearest hospital:

- Drowsiness
- Skin rash
- low blood pressure, a temporary blur of consciousness

These are serious side effects, you may need medical intervention.

If you notice some of the following symptoms, call your doctor immediately:

- nausea
- vomiting
- Diarrhea
- abdominal pain

These are the mild side effects of Muscoflex.

These side effects will go away when you reduce the dose or upon discontinuation of therapy. If you notice any of these side effects, please inform your doctor or pharmacist.

In rare or very rare cases, you may experience other less serious side effects. If you would like to receive additional information about these side effects, please ask your doctor or pharmacist.

If you notice any side effects not mentioned in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE MUSCOFLEX

Keep out of sight and reach of children.

Store at temperature below 25°C.

Keep Muscoflex 8 mg hard capsules in the original packaging, tightly closed because they are sensitive to moisture.

Muscoflex 8 mg hard capsules should not be used after the expiry date indicated on the package.

6. FURTHER INFORMATION:

Each Muscoflex capsule contains up to 8 mg of thiocolchicoside as an active ingredient.

Extra ingredients: lactose monohydrate, maize starch, magnesium stearate, purified colors.

Extra ingredients in Capsule: gelatine, sodium lauryl sulfate, titanium dioxide, karmoisin (E122) and indigo Carmine.

10 or 20 gelatin capsules are packaged in pairs in transparent, solid package, and then in the A1 PVC blisters along with instructions for use in cardboard boxes.

Regime of dispensing

The medicine is issued on doctor's prescription

Manufacturer

BILIM ILAC SANYII VE TICARET A.S.

AYAZAGA KOYU YOLU G• 24 SOK, No 6,

MASLAK, ISTANBUL /TURKEY

Manufacturer of the medicinal product

BILIM ILAC SANAYII VE TICARET A.S.

Gebze Organize Sanayi Bolgesi 1900 Sokak (GOSB)

41480 Gebze KOCAELI /TURKEY