

PATIENT INFORMATION LEAFLET

Thiocolchicoside Capsules IP
(4mg/ 8mg)

THIOMUS 4/8

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 or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

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

1. What THIOMUS is and what it is used for

THIOMUS contains the active substance Thiocolchicoside. The primary effect of THIOMUS is characterized by a muscle relaxation. THIOMUS is used for the symptomatic treatment of painful muscle spasms.

2. What you need to know before you take THIOMUS

Do not take THIOMUS

- ❖ If you are allergic to THIOMUS.
- ❖ If the muscles do not work (there is no possibility of contraction).

If any of the above applies to you, do not take THIOMUS and talk to your doctor.

Warnings and precautions:

Talk to your doctor before taking THIOMUS.

Take special care with THIOMUS and tell your doctor if you:

- ❖ Are epileptic or have a risk of seizures.
- ❖ Have diarrhea during the administration of this product
- ❖ You should not use this medicine at higher dose or for longer than 7 days. This is because one of the products formed in your body when taking thiocolchicoside at high doses might cause damage to some cells (abnormal number of chromosomes). This has been shown in studies in animals

and in laboratory studies. In humans, this type of damage to cells is a risk factor for cancer, harm to the unborn child, and impairment of male fertility.

- ❖ Please discuss with your doctor if you have further questions. Your doctor will inform you about all measures relating to an effective contraception and about the potential risk of a pregnancy.

Children and adolescents

THIOMUS is only for adults and should not be taken by children and adolescents below 16 years.

Other medicines and THIOMUS

Tell your doctor if you are taking, or have recently taken, or might take any other medicines.

THIOMUS may affect the way other medicines work, and other medicines may affect how this medicine works.

- ❖ 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.

Pregnancy and breast-feeding

THIOMUS is not recommended for use during pregnancy.

- ❖ Tell your doctor if you are pregnant or planning to become pregnant.
- ❖ If you are breast-feeding, ask your doctor or pharmacist for advice before taking this medicine.
- ❖ It is likely that this medicine passes into your breast milk. You and your doctor should decide if you should take THIOMUS or breast-feed. You should not do both.

Ask your doctor for advice before taking any medicine.

Driving and using machines

There is no information to suggest that this medicine affects your ability to drive or use machines. Be careful driving or operating machinery until you know how THIOMUS affects you. It may cause drowsiness in some people. If this occurs, do not drive or use machinery.

3. How to take THIOMUS

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

The recommended dose is one capsule (thiocolchicoside 4 mg/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.

Do not exceed the recommended doses and treatment duration.

If you take more THIOMUS than you should

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

If you forget to take THIOMUS

Then take the missed dose as soon as you remember.

Do not take a double dose to make up for a forgotten dose. If you miss several doses, tell your doctor and follow the advice given to you.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects mostly occur at the start of treatment and usually disappear within a few days with continued treatment.

Tell your doctor or pharmacist if you notice or have any of the following:

Common: may affect up to 1 in 10 people

- ❖ Nausea
- ❖ Vomiting
- ❖ Abdominal Pain
- ❖ Dizziness
- ❖ Diarrhoea

Uncommon: may affect up to 1 in 100 people

- ❖ Drowsiness
- ❖ Skin rash
- ❖ Low blood pressure
- ❖ Temporary blur of consciousness

Very rare side effects (may affect up to 1 in 10,000 people)

- ❖ Swelling of the arms, legs, ankles, face, lips, or mouth, throat
- ❖ Itching, swelling of the mucous membranes (angioneurotic edema)
- ❖ Fainting (vasovagal syncope)
- ❖ Rashes on the skin

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

5. How to store THIOMUS

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

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Protect this medicine from light and moisture.

Store this medicine below 30° C.

Do not throw away any medicines via waste water. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What THIOMUS 4/8 contains

The active ingredient of THIOMUS is Thiocolchicoside.

THIOMUS 4

Each hard gelatin capsule contains:

Thiocolchicoside IP 4 mg

Approved colours used in capsule shells.

THIOMUS 8

Each hard gelatin capsule contains:

Thiocolchicoside IP 8 mg

Approved colours used in capsule shells.

What THIOMUS 4/8 looks like and contents of the pack

THIOMUS 4 capsules are hard gelatin capsule of size "2" with "THIOMUS 4" and "Q" logo printed on white body and yellow cap respectively. Capsules are packed into PVDC Blister. The pack size is 10 x 10 capsules in a printed paper carton along with packing insert.

THIOMUS 8 capsules are hard gelatin capsule of size "2" with "THIOMUS 8" and "Q" logo printed on green body and yellow cap respectively. Capsules are packed into PVDC Blister. The pack size is 10 x 10 capsules in a printed paper carton along with packing insert.



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