

PATIENT INFORMATION LEAFLET

TIORELAX 8 mg Tablets

Taken by mouth.

- **Active Substance:** 8 mg Thiocolchicoside
- **Excipients:** Lactose monohydrate, microcrystalline cellulose, pregelatinized starch, copovidone, colloidal silicon dioxide and magnesium stearate.

▼ This medicinal product is subject to additional monitoring. This triangle will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this Patient Information Leaflet carefully before you start using this medicine because it contains important information for you.

- *Keep this Patient Information Leaflet. You may need to read it again.*
- *If you have any further questions, please ask your doctor or pharmacist.*
- *This medicine has been prescribed for you personally and you should not pass it on to others.*
- *When you see a doctor or to go to hospital while taking this medicine, tell your doctor that you are using this medicine.*
- *Precisely follow these instructions. Do not take **lower or higher** doses than the recommended dose.*

In This Leaflet:

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- 2. What you need to know before you use TIORELAX?**
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1. What TIORELAX is and what it is used for?

TIORELAX is in tablet form and contains 8 mg of thiocolchicoside as the active substance.

TIORELAX is presented in blister packages containing 14 tablets. Yellow, round, biconvex tablets, imprinted with “8” on one side and scored on the other side. (The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses, the tablet may be divided into equal halves).

TIORELAX has mainly muscle relaxant activity. TIORELAX is used in adults and adolescents from 16 years onwards for the treatment of sudden painful muscular contractions related to spinal column.

2. What you need to know before you use TIORELAX

Do not use TIORELAX

If:

- A muscle or muscles not functioning (cannot contract),
- You are hypersensitive to the active substance or any of the other ingredients,
- You are pregnant or breastfeeding,
- You might become pregnant and you are not using an effective birth control method,
- If you are under 16 years age.

Take special care with TIORELAX :

If:

- If you are epileptic or if you have a risk of epileptic seizures,

One of the products formed in your body when taking TIORELAX 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. For this reason, strictly respect the doses and duration of treatment detailed in section “Instruction for proper use and dosage/administration frequency”. You should not use this medicine at higher dose or for longer than 7 days. Please discuss with your doctor if you have further questions.

Liver problems may occur during treatment with TIORELAX. If any of the following symptoms occur, contact your doctor immediately: pain or discomfort in the stomach (abdominal) area, loss of appetite, nausea, vomiting, yellowing of the skins or eyes (jaundice), darker than normal urine, itching, as well as fever and tiredness (especially if accompanied by the symptoms mentioned earlier). These may be signs of liver problems.

If diarrhea occurs during treatment, discontinue treatment with TIORELAX.

Please consult your doctor even if any of the above applies to you, even at any time period in the past.

Taking TIORELAX with food and drink

TIORELAX does not show any interaction with food and drink.

Pregnancy

Consult your doctor or pharmacist before taking this medicine.

Do not take this medicine if you are pregnant.

Commit your doctor or pharmacist immediately if you find out you are pregnant during your treatment.

Breastfeeding

Consult your doctor or pharmacist before taking this medicine.

Do not take this medicine if you are breastfeeding.

Driving and using machinery

According to clinical studies, thiocolchicoside has no effect on (psychomotor) performance, which is related to motor effects due to mental activity. Because this medicine may commonly cause somnolence and drowsiness, be careful while driving and using machines.

Important information on some excipients present in TIORELAX

Each TIORELAX 8 mg tablet contains 67.68 mg of lactose. If you have been told by your doctor that you have intolerance to some sugars, you should contact your doctor before taking this medicinal product.

Concomitant use with other medicines**Taking with other medicines**

· TIORELAX, is not recommended to be taken concomitantly with other medicines that have muscle relaxant effect on the musculoskeletal system, because they may potentiate the effects of each other. For the same reason, if taken concomitantly with another medicine that has an effect on the smooth muscles, caution should be exercised against the possibility of increased incidence of adverse effects.

Please note that this warning may apply to the products used at a previous time and the products to be used at any time in the future.

Please tell your doctor or pharmacist about any medicines, prescription or non-prescription, you are currently taking or have recently taken.

3. How to use TIORELAX**Instructions for proper use and dosage/administration frequency:**

· The recommended and maximal dose is 1 tablet (8 mg of thiocolchicoside) taken 2 times per day every 12 hours (with 12- hour intervals). So do not take more than 2 TIORELAX tablets (a total of 16 mg thiocolchicoside) per day.

· Normally, treatment with TIORELAX 8 mg tablet takes 5-7 days. Do not use for more than 7 consecutive days.

Route and method of administration:

- TIORELAX is intended for oral use only. Do not chew the tablets.
- Take the tablets with sufficient amount of water (e.g. a glass of water) after meals.

Do not exceed the recommended dose and do not use.

Follow these instructions unless otherwise recommended by your doctor.

Do not forget to take your medication in due time.

Your doctor will tell you how long your treatment with TIORELAX will continue.

Do not stop your treatment earlier because you can not get the desired result.

Different age groups**Use in children:**

Do not give this medicine in children below 16 years old.

Use in elderly:

The safety and efficacy of TIORELAX in elderly patients have not been studied.

Special use conditions**Kidney / Liver impairment :**

The safety and efficacy of TIORELAX in patients with kidney/liver impairment have not been studied.

If you have the impression that the effect of TIORELAX is too strong or weak, talk with your doctor or pharmacist.

If you use more TIORELAX than you should

If you used more TIORELAX than you should, talk to a doctor or pharmacist.

If you forget to use TIORELAX

Do not take double dose to make up for a forgotten dose.

The effects that may occur if treatment with TIORELAX is stopped

None.

4. Possible side effects

Like all medicines, side effects may occur in persons who are sensitive to the ingredients of TIORELAX.

Stop taking TIORELAX and contact your doctor IMMEDIATELY or go to the emergency department of the nearest hospital if you notice any of the following

- Swelling of the hands, feet, 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)
- Convulsion (seizure)

All of this are very serious side effects.

If you experience any one of these side effects, than you have a serious allergy to TIORELAX. You may require emergency medical intervention or hospitalization.

All of these very serious side effects occur very rarely.

Contact your doctor immediately or go to the emergency room of the nearest hospital if you notice any of the following side effects

- Pain or discomfort in the stomach (abdominal) area, loss of appetite, nausea, vomiting, yellowing of the skin or eyes (jaundice), darker than normal urine, itching, fever and tiredness (these may be signs of liver problems).
- Drowsiness, somnolence,
- Itching,
- Skin rushes,
- Low blood pressure, a temporary blurring of consciousness, expansiveness,

All of these are serious side effects. Emergency medical interventions may be required. Serious side effects are very rarely.

If you notice any of the following side effects, tell your doctor:

- Nausea,
- Vomiting,
- Diarrhea
- Stomachache.

These are mild side effects of TIORELAX

These side effects subside when the dose is reduced or treatment discontinued.

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

Reporting side effects

If you get any side effects, listed or not listed in this leaflet, talk to your doctor, pharmacist or nurse. Also report the side effect you are experiencing to Turkish Pharmacovigilance Center (TUFAM) by clicking on the icon "Drug Side Effects Reporting" on www.titck.gov.tr or by calling the side effects reporting line on 0 800 314 00 08. By reporting side effects that occur you will contribute to obtaining more information on the safety of this medicine you are taking.

5. How to store TIORELAX

Keep TIORELAX out of the reach and sight of children and in the original package.

Store below 25°C.

Take in accordance with the expiry date.

Do not use TIORELAX after the expiry date printed on the package.

Do not use TIORELAX if you notice defects on the product and/or its packaging.

Issue:

Pharmaceutical product group II, issued of prescription form N3.

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This leaflet has been approved <{DD month YYYY}>.

[To be completed nationally]