

PATIENT INFORMATION LEAFLET

TIORELAX® 4 mg tablet

For oral use.

- **Drug Substance:** 4 mg thiocolchicoside in each tablet.
- **Excipients:** Lactose monohydrate of bovine origin, microcrystalline cellulose, pregelatinized starch, crospovidone, colloidal silicon dioxide and magnesium stearate.

▼ This medicinal product is subject to additional monitoring. This 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, ask your doctor.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *During the use of this product, tell your doctor that you use this medicinal product.*
- *Strictly follow these Patient Information Leaflet. Do not take **lower or higher** doses than the recommended dose.*

In this leaflet:

- 1. What TIORELAX® is and what it is used for?**
- 2. What you need to know before you use TIORELAX®**
- 3. How to use TIORELAX®?**
- 4. Possible side effects**
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1. What TIORELAX® is and what it is used for?

TIORELAX® is in tablet form and contains 4 mg of thiocolchicoside as the active ingredient. TIORELAX® is presented in a cardboard box containing 20 tablets in blister packaging. Yellow, round, biconvex tablet, debossed “4” on one face and scored on the other face. (The score line 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 of age to treat acute painful muscular contractions related to spinal column.

TIORELAX® contains lactose monohydrate of bovine origin.

2. What you need to know before you use TIORELAX®

Do not use TIORELAX® if:

- The muscles do not work (there is no possibility of contraction),
- You are hypersensitive to thiocolchicoside or any of the other ingredients of this medicine
- You are pregnant or breastfeeding,
- You might become pregnant and use an effective contraception method.
- You are younger than 16.

Take special care with TIORELAX® if:

- You are epileptic or have a risk of 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. Therefore, 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 to you, tell your doctor immediately: Pain or discomfort in the stomach (abdominal) region, loss of appetite, nausea, vomiting, redness in skin or eye circles (jaundice), urine darker than normal, pruritus, as well as fever and fatigue (especially accompanied with those mentioned above). These may be signs of liver problems.

If diarrhea occurs during treatment, discontinue treatment with TIORELAX®.

Please consult your doctor even if these warnings apply to you at any time in the past.

Taking TIORELAX® with food and drink

TIORELAX® does not show any interaction with food and drink.

Pregnancy

Before using this medicine consult your doctor or pharmacist.

Do not take this medicine if you are pregnant.

If you notice that you have been pregnant during treatment, consult immediately your doctor or pharmacist.

Breastfeeding

Before using this medicine consult your doctor or pharmacist.

Do not take this medicine if you are breastfeeding.

Driving and using machinery

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.

Important information regarding some excipients present in TIORELAX®

Each tablet of TIORELAX® 4 mg contains 33,84 mg lactose. If you have previously been told by your doctor that you have intolerance to certain sugars, you should consult your doctor before taking this medicinal product.

Taking with other medicines

- Concomitant administration of TIORELAX® 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.

Please note that this warning may also apply to products that have been used for a certain period of time or that will be used in the future.

If you are taking or have recently taken any other medicines, including medicines without a prescription, tell your doctor or pharmacist.

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

- The recommended and maximal daily dose is 2 tablets (8 mg thiocolchicoside) twice a day, every 12 hours (with 12 hours interval). So do not use more than 4 tablets of TIORELAX® a day (total 16 mg thiocolchicoside).
- Normally, treatment with TIORELAX® 4 mg tablet takes 5-7 days. Do not use for more than 7 days.

Route and method of administration:

- TIORELAX® is intended for oral use only. Do not chew the tablets.
- Take the tablets with enough water (eg. One glass of water), after meals.

Do not exceed the recommended dose and do not use for long-term treatment.

Follow these instructions unless otherwise recommended by your doctor.

Do not forget to take your medication on time.

Your doctor will inform you on the duration of your treatment with TIORELAX®. Do not stop your treatment early because you can not get the desired result.

Different age groups**Use in children:**

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

In elderly:

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

Special usage**Renal / Hepatic Failure:**

The safety and efficacy of TIORELAX® have not been studied in patients with renal/hepatic failure.

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 was prescribed, tell your doctor or pharmacist.

If you forget to use TIORELAX®

Do not take double dose to make up the dose you have missed.

Effects that may occur if you stop taking TIORELAX®

Not applicable.

4. Possible side effects

Like all medicines, TIORELAX® may cause side effects in patients sensitive to its ingredients.

If any of the following reactions happen, stop taking TIORELAX® and tell your doctor immediately or contact the casualty department at your nearest hospital

- 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)

These are all very serious side effects.

If you experience one of these side effects, it means that you are severely allergic to TIORELAX®.

You may need urgent medical attention or to be hospitalized.

These very serious side effects are all rare.

If you notice any of the following side effects, tell your doctor immediately or contact the casualty department at your nearest hospital

- Pain or discomfort in the stomach (abdominal) region, loss of appetite, nausea, vomiting, redness in skin or eye circles (jaundice), urine darker than normal, itching, fever and fatigue (these may be signs of liver problems),
- Drowsiness, somnolence,
- Itching,
- Skin rash,
- Low blood pressure, a temporary blur of consciousness, exuberance

These are all serious side effects. You may need urgent medical attention.

Serious side effects are very rare.

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

- Nausea,
- Vomiting,
- Diarrhoea
- Abdominal pain.

These are mild side effects of TIORELAX®

These side effects will go away when you reduce the dose or upon discontinuation of therapy.

Tell your doctor or pharmacist if you notice any other effects not listed in this leaflet.

Reporting side effects

Please inform your doctor, pharmacist or nurse if you get any side effect whether or not included in this leaflet. In addition, please report the side effect that you are experiencing to Turkish Pharmacovigilance Center (TÜFAM) by clicking to the icon "Reporting Drug Side Effects" at www.titck.gov.tr or call the reporting hotline dialing 0 800 314 00 08. By reporting the side effects, you can help provide more information on the safety of this medicine.

5. How to store TIORELAX®

Store TIORELAX® in its original packaging and keep out of the reach and sight of children.
Store at room temperature below 25°C.

Use in compliance with the expiry date

Do not use TIORELAX® after the expiry date which is stated on the packaging.

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

Do not throw away drugs that have expired or are not used!

Deliver to the collection system determined by the Ministry of Environment and Urbanism.

Marketing Authorisation Holder:

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