Relief®

Thiocolchicoside

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT
RELIEF® 4 mg Capsule, hard
RELIEF® 4 mg/2ml Solution for injection
Thiocolchicoside

▼ This medicine 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 on how to report side effects

Read 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you notice any side effects inform your doctor or pharmacist or nurse. This also applies to any possible side effects not listed in this leaflet. See section 4.

What does this leaflet contain:

1. What is RELIEF® and what it is used for

This medicine is a muscle relaxant. It is used in adults and adolescents from 16 years onwards as an adjuvant treatment for painful muscular contractions. It is to be used for acute conditions related to spinal column.

2. What information do you need to know before taking RELIEF®

Do not take RELIEF®:
- if you are allergic to thiocolchicoside or to any of the other ingredients of this medicine (listed in section 6)
- if you are pregnant, might become pregnant or think you may be pregnant
- if you are a woman of childbearing potential not using contraception
- if you are breast feeding
- in case of flaccid paresis, muscular hypotonia

RELIEF® should not be used in children.

Warnings and precautions

When you take this medicine, problems in the liver may occur. Inform your doctor immediately if you experience any of the following signs and symptoms that indicate liver problems: Pain in the stomach area (abdominal area) or discomfort, anorexia, nausea, vomiting, yellowing of the skin or whites of the eyes (jaundice), unusually dark urine, itching, as well as fever and fatigue (particularly in combination with other symptoms listed above) (see. section 4).

Capsules: Due to the presence of lactose, patients with rare hereditary lactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.
In case of diarrhea, treatment with RELIEF® must be discontinued.
Injectable solution: Cases of fainting of vasomotor origin have been observed, therefore the patient should be monitored following the injection (see. Section 4).
Strictly respect the doses and duration of treatment detailed in section 3.
You should not use this medicine at higher dose or for longer than 7 days (for oral formulations) / 5 days (for intramuscular formulations). 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 proved in studies with 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

Do not give this medicine to children and adolescents below 16 years old because of safety concerns.

Other medicines and RELIEF®

Inform your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
It may display a synergistic effect if administered together with other muscle relaxants, or central nervous system sedatives.

Pregnancy, breast-feeding and fertility

Do not take this medicine if:
- you are pregnant, might become pregnant or think you may be pregnant
- you are a woman of childbearing potential not using contraception

This is because this medicine may harm your unborn child.
Do not take this medicine if you are breast-feeding.
This is because the medicine passes into your breast-milk.
This medicine might cause problems to the male fertility due to potential damage to sperm cells (abnormal number of chromosomes). This is based on laboratory studies (see section 2 "Warnings and precautions").

Driving vehicles and using machinery

Clinical studies show that RELIEF® has no effect on psychomotor performance. However, because drowsiness can often occur, this should be taken into consideration when driving vehicles and operating machines.

3. How to take RELIEF®

Always take this medicine exactly as your doctor or pharmacist has told you. Ask your doctor or pharmacist if you have any doubts.

- *For the oral form of 4 mg:* The recommended and maximum dose is 8 mg every 12 hours (ie. 16 mg per day). The treatment duration is limited to 7 consecutive days.
- *For intramuscular form:* The recommended and maximum dose is 4 mg every 12 hours (ie. 8 mg per day). The treatment duration is limited to 5 consecutive days.
- *For oral and intramuscular form:*

Do not exceed the recommended dose and treatment duration.

This medicine should not be used for long term treatment (see. Section 2 "Warnings and precautions").

Use in children and adolescents

Do not give this medicine to children and adolescents below 16 years old because of safety concerns.

If you take a higher dose of RELIEF® than normal

If you accidentally take a higher dose of RELIEF® than you should, contact your doctor, pharmacist or nurse.

If you forget to take RELIEF®

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

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.

The following frequency scale by CIOMS is used: Very common (≥ 10%), common (≥ 1% to <10%), uncommon (≥ 0.1% to <1%), rare (≥ 0.01% to <0.1%), very rare (<0.01%), not known (cannot be estimated from the available data).

Immune system disorders

Anaphylactic reactions including

Uncommon: Itching

Rare: Urticaria

Not known: Angioedema, anaphylactic shock following IM injection.

Nervous system disorders

Common: Drowsiness

Not known: Fainting of vasomotor origin usually occurring few minutes following IM injection (see. Section 2) spasms (see. Section 2).

Gastrointestinal disorders

Common: Diarrhoea (see. Section 2), gastralgia,

Uncommon: Nausea, vomiting.

Hepato-biliary disorders

Not known: cytolytic and cholestatic hepatitis (see. Section 4.4. "Special warnings and precautions for use")

Skin and subcutaneous tissue disorders

Uncommon: Allergic skin reactions.

Reporting of adverse reactions:

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 to:

· National Organization for Medicines, Mesogeion 284, GR-15662 Cholargos, Athens, **www.eof.gr,**
Tel: + 30 213 2040380/337, Fax: + 30 210 6549585

· Pharmaceutical Services, Ministry of Health, CY-1475, **www.moh.gov.cy/phs** Fax: + 357 22608649

· Malta Medicines Authority, 203, Level 3, Rue D'Argens Road, Gzira GZR 1368, Malta, Tel: +356 23439000, Fax: +356 23439161 or **www.medicinesauthority.gov.mt/adrportal**

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

5. How to store RELIEF®

Keep out of the reach and sight of children.

The product should be stored at room temperature (15°C -25°C).

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

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer used. These measures will help to protect the environment.

6. Package Content and Further information

What does RELIEF® contain

- The active substance is Thiocolchicoside
- The other ingredients are:

Capsules:

Lactose monohydrate, Maize starch, Magnesium stearate

Composition of empty capsule No 2 (white – green)

Titanium dioxide E 171, Quinoline yellow E 104, Indigo carmine E132, Gelatine.

Injectable solution:

Sodium chloride, Water for injections

Formulations & Package content of Relief®

Capsules: White-green coloured capsules packed in blisters of PVC /PVDC and aluminum foil. The product characteristics and lot number are printed on each blister. Each blister contains 10 capsules. Each carton contains 2 or 3 blisters i.e. 20 or 30 capsules, and a patient information leaflet.

Solution for injection: Sterile yellowish solution for injection packaged in clear glass ampoules. The product characteristics and lot number are printed on every ampoule that contains 2ml solution. The ampoules are placed in a plastic case with 5 places. Every carton contains 2 plastic cases with 5 ampoules and one patient information leaflet.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder – Holder of Special Marketing Authorisation in Cyprus

IASIS PHARMA
137, Filis Ave,
134 51, Kamatero, Athens, Greece
Tel.: +30 210 2311031

Manufacturer

RELIEF® Capsules:

IASIS PHARMA, 137, Filis Ave, 134 51,
Kamatero, Athens

RELIEF® Solution for injection:

KLEVA S.A., 189, Av. Parnithos 136 71, Acharnes – Attiki
ANFARM HELLAS S.A., Sximatari Viotias, 32009, Greece

This leaflet text was last revised in October 2014.