

Relief[®]

Thiocolchicoside



GEL

PATIENT INFORMATION LEAFLET

1. DETERMINATION OF THE PHARMACEUTICAL PRODUCT

1.1 Name: RELIEF

1.2 Composition: Active ingredient: Thiocolchicoside

Excipients: Ethanol 95°, Trolamine, Carbopol 980, Water purified.

1.3 Pharmaceutical form: Gel

1.4 Content in active agent: Each gram of gel contains 2.5 mg thiocolchicoside (percentage of 0.25% w/w)

1.5 Description – Packaging: Yellowish gel packaged in aluminum tube with plastic screwed cap. The tube bears the characteristics of the product and the lot printed and contains 60 gr of gel. Each box contains a tube and a patient information leaflet.

1.6 Pharmacotherapeutic category: Muscle relaxant acting centrally

1.7 Marketing Authorization Holder – Manufacturer: IASIS PHARMA HELLAS S.A., 137, Filis Ave., 134 51 Athens, Greece. Tel: +30 210 2311031

2. WHAT YOU NEED TO KNOW ABOUT THE MEDICINE PRESCRIBED BY YOUR DOCTOR

2.1 General information

RELIEF contains the active agent thiocolchicoside, which brings a progressive relaxation of the muscles in rheumatic conditions accompanied by muscular spasm.

2.2 Indications

Possibly effective as adjuvant treatment for the relief of muscular pain accompanying conditions such as:

- Acute or chronic rheumatopathy, inflammatory or not, such as: rheumatoid arthritis, osteoarthritis, ankylopoietic arthritis, lumbago or ischialgia
- Pain from muscular spasm

2.3 Contraindications:

- Known hypersensitivity to thiocolchicoside or any of the excipients
- Pregnancy and lactation (see 2.4.2 and 2.4.3 "Pregnancy and lactation")
- Flaccid paresis, muscular hypotonia
- Children

2.4 Special precautions and warnings for use

2.4.1 General:

Precautions: Lowering of the dose is required in the case of diarrhoea.

Warnings: RELIEF can predispose to spasm in patients with epilepsy or patients at risk for seizures.

2.4.2 Pregnancy: Contraindicated during pregnancy

2.4.3 Lactation: Contraindicated during lactation

2.4.4 Effects on ability to drive and use machines: Due to the insignificant absorption in local applications, no systematic effects are expected. Caution is recommended for possible suppressing effect before driving and using machines.

2.4.5 Children: See 2.6. "Posology and method of administration"

2.4.6 Special warnings for the contained excipients: Not applicable

2.5 Interactions with other medicines or substances

Not applicable

2.6 Posology and method of administration:

Method of administration: Skin use

Posology: The posology is customized according to each patient's needs.

1 - 3 applications per day with a small quantity which is quickly absorbed without rubbing

Children: The use of RELIEF gel is not recommended for children less than 15 years.

2.7 Overdose - Treatment:

Points and symptoms: No overdose expected in this pharmaceutical form

Treatment: In case of intentional swallowing, application of general measures and symptomatic treatment are recommended.

2.8 Undesirable effects

Immune system disorders: Anaphylactic reactions, such as pruritus, urticaria, angioedema

Nervous system disorders: Lassitude

Skin and subcutaneous tissue disorders: Skin allergic reactions, including photosensitivity

2.9 What you should know if you omit to take a dose

If you take the medicine regularly and you omit a dose, you should take it as soon as possible. If, however, the time for the next dose is close, do not take the omitted dose, but continue the treatment as scheduled.

Do not take double doses.

2.10 What you should know about the expiry date of the product

Written on the inner and outer package. If the expiry date has elapsed, do not use the medicine.

2.11 Special precautions for the storage of the product

This medicine should be stored at room temperature away from children.

2.12 Last revision date of the package leaflet: 26-4-2010

3. INFORMATION FOR THE RATIONAL USE OF MEDICINES

· This medicine has been prescribed by your doctor only for your specific medical problem. You must not pass it on others or use it for any other condition without having asked your doctor first.

· If during the treatment, a problem arises with the medicine, inform your doctor or pharmacist immediately.

· If you have any inquiries about the information concerning the medication you take or you need more information about your medical problem, do not hesitate to ask your doctor or your pharmacist for this information.

· The medicine should be taken according to the instructions given so that it can be effective and safe.

· For your own safety and health it is necessary to read the information concerning the prescribed medicine carefully.

· Do not keep medicines in bathroom drawers because heat and humidity can spoil the medicine and make it harmful for your health.

· Do not keep medicines you do not need any more or have already expired.

· For more safety, keep all medicines in a safe place out of reach of children.

4. DISPENSATION: Prescription medicine