

Corelex Injection/Capsule

(Thiocolchicoside)

کورلیکس انجیکشن / کپسول
(تھائیکولچیکوسائیڈ)

COMPOSITION:

Corelex Capsules 4mg

Each capsule contains:

Thiocolchicoside (MS).....4mg

Corelex Injection 4mg

Each 2ml contains:

Thiocolchicoside (MS).....4mg

Products comply Innovator's specs.

DESCRIPTION:

The active component in CORELEX is thiocolchicoside. Thiocolchicoside is a muscle relaxant with anti-inflammatory and analgesic effects. It acts as a competitive GABA-A receptor antagonist and also glycine receptor antagonist with similar potency and nicotinic acetylcholine receptors to a much lesser extent. It has powerful convulsant activity and should not be used in seizure-prone individuals.

MODE OF ACTION:

Thiocolchicoside is a semi-synthetic sulphurated derivative of colchicoside, with myorelaxant pharmacological activity. In-vitro, thiocolchicoside only binds to GABA-A and strychnine-sensitive glycine receptors. Thiocolchicoside acting as a GABA-A receptor antagonist, its myorelaxant effects could be exerted at the supraspinal level, via complex regulatory mechanism, although a glycinergic mechanism of action cannot be excluded. The characteristics of the interaction of thiocolchicoside with GABA-A receptors are qualitatively and quantitatively shared by its main circulating metabolite, the glucuronidated derivative.

INDICATIONS:

As an adjuvant treatment in painful spasm associated with degenerative vertebral disorders, dorsal pain, lowback pain, torticollis, traumatological and neurological disorders It is thought to act on receptors in the nervous system that are involved in the regulation of muscle function.

DOSEAGE AND ADMINISTRATION:

General

For oral use: The recommended and maximal dose is 8 mg every 12 hours (i.e. 16 mg per day). The treatment duration is limited to 7 consecutive days.

For IM use: The recommended and maximal dose is 4 mg every 12 hours (i.e. 8 mg per day). The treatment duration is limited to 5 consecutive days.

Applies to oral and IM forms:

Doses exceeding recommended doses or long-term use should be avoided.

Special Populations

Children

Thiocolchicoside is not recommended for use in children below the age of 16 years.

PHARMACOKINETICS

Thiocolchicoside is broken down in the body to a metabolite called 3-demethylthiocolchicine (also known as SL59,0955 or M2) that could damage dividing cells therefore inducing toxicity in the embryo, neoplastic changes and fertility reduction in males. Therefore, recommended oral dose should not exceed 7 days and intramuscular dose duration should not exceed 5 days. Local skin preparations are less toxic.

PRECAUTIONS & WARNINGS

Warnings

Applies to the oral and IM form only:

In preclinical studies, one of thiocolchicoside metabolites (SL59,0955) induced aneuploidy (i.e. unequal number of chromosomes in dividing cells) at concentrations close to human exposure observed at doses 8 mg twice daily per os. Aneuploidy is reported as a risk factor for teratogenicity, embryo foetotoxicity/spontaneous abortion, cancer, and impaired male fertility. As a precautionary measure, use of the product at doses exceeding the recommended dose or long-term use should be avoided. Post marketing cases of cytolytic and cholestatic hepatitis have been reported with thiocolchicoside. Severe cases (i.e., fulminant hepatitis) have been reported in patients concomitantly taking NSAIDs or paracetamol. Patients should be advised to report any sign of liver toxicity. Thiocolchicoside may precipitate seizures, especially in patients with epilepsy or those at risk for seizures.

Patients should be carefully informed about the potential risk of a possible pregnancy and about effective contraception measures to be followed.

Applies to formulations containing lactose/saccharose only:

Due to the presence of lactose, patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Due to the presence of saccharose, patients with rare hereditary problems of fructose intolerance should not take this medicine.

Precautions

Applies to the oral and IM form only:

In case of diarrhea the treatment with thiocolchicoside should be stopped.

Applies to the IM form only:

Cases of syncope vasovagal have been observed and therefore, the patient should be monitored after the injection.

Pregnancy:

Studies conducted in animals have shown a reproductive toxicity including teratogenic effects.

There are insufficient clinical data to evaluate safety of use in pregnancy. Thus, the potential hazards for the embryo and fetus are unknown. In consequence, thiocolchicoside is contraindicated in pregnancy and women of childbearing potential who are not using effective contraception.

Lactation:

Since it passes into the mother's milk, the use of thiocolchicoside is contraindicated during breast feeding.

Driving a vehicle or performing other hazardous tasks:

There are no data available of the effect on driving vehicles and using machines. Clinical studies concluded that thiocolchicoside has no effect on the psychomotor performance. However, somnolence may occur commonly, this has to be taken into account when driving vehicles and operating machines.

ADVERSE REACTIONS:

General

Sedation, drowsiness, blurred or double vision, constipation or diarrhea, dizziness and drowsiness, nervousness and confusion, dry mouth, dyspepsia, fatigue, headache, heartburn, hiccups and nausea, insomnia, stomach cramps, trembling, vomiting, and weakness.

Immune system disorders

Anaphylactic reactions, such as:

Uncommon: pruritus,

Rare: urticaria,

Unknown: angioneurotic oedema, anaphylactic shock following intramuscular injection.

Nervous system disorders

Common: somnolence,

Unknown: syncope vasovagal, usually occurring in the minutes following the intramuscular injection, convulsions.

Gastrointestinal disorders

Common: diarrhea, gastralgia,

Uncommon: nausea, vomiting,

Hepatobiliary disorders

Unknown: cytolytic and cholestatic hepatitis.

Skin and subcutaneous tissue disorders

Uncommon: allergic skin reaction.

INTERACTION:

No known interaction has been reported.

OVERDOSE:

Signs and Symptoms: No specific symptoms of overdose have been reported in patients treated with thiocolchicoside.

Management: If over dosage occur, medical supervision and symptomatic measures are recommended.

CONTRAINDICATIONS:

Known hypersensitivity to thiocolchicoside or to any excipients in the formulation. In women of childbearing potential who are not using effective contraception.

STORAGE & INSTRUCTIONS:

Store between 15-25°C.

Protect from heat, sunlight and moisture.

Keep away from the reach of children.

To be sold on the prescription of a registered medical practitioner only.

HOW SUPPLIED:

Corelex 4mg Capsule: 10's, 20's Capsules

Corelex 4mg Injection: 6 ampoules

خوراک و طبیقیقہ استعمال:

ڈائریکٹ ہدایت کے مطابق استعمال کریں۔

ہدایات:

15-25°C اور 5-15°C کے درمیان رکھیں۔

دھوپ، گرمی اور دھول سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

صرف رجسٹرڈ ڈاکٹرن کے مطابق فرمٹ کریں۔

Manufactured by:
PHARMASOL
PRIVATE LIMITED

Plot # 549, Sundar Industrial Estate,
Lahore, Pakistan.