

Colchid[®] 4mg Capsules

(Thiocolchicoside)

Colchid Capsules:

Each capsule contains:

Thiocolchicoside 4 mg

CLINICAL PHARMACOLOGY

Pharmacodynamics: 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 can not 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

Pharmacokinetics:

Thiocolchicoside is rapidly adsorbed after oral administration, and metabolized into 3 main metabolites. The two main circulating forms were the thiocolchicoside aglycon and the glucuronidated derivative of thiocolchicoside, which is active. The active glucuronidated derivative of thiocolchicoside is also observed after intramuscular administration. In humans, the binding of thiocolchicoside to human serum proteins is low (13%) and not dependent on the therapeutic concentration of thiocolchicoside and serum albumin is mainly involved in serum protein binding. After a single 8 mg oral administration of thiocolchicoside, the mean area under the curve (AUC) of the active glucuronidated metabolite, which reflects exposure to the active entities, is about 126ng.h/mL. After oral administration of (14C)-radiolabelled thiocolchicoside, 79% of the dose is recovered in faeces and 20% in urine.

INDICATIONS AND USAGE

Adjuvant treatment of painful muscle contractures in acute spinal pathology in adults and adolescents from 16 years onwards.

CONTRAINDICATIONS

Thiocolchicoside must not be used

- in patients hypersensitive to the active substance or to any of the excipients.
- during the entire pregnancy period
- during lactation
- in women of childbearing potential not using contraception

INTERACTIONS

Not Known

USE IN SPECIFIC POPULATION

Pregnancy: There are limited data on the use of thiocolchicoside in pregnant women. Therefore, the potential hazards for the embryo and foetus are unknown. Studies in animals have shown teratogenic effects. Colchid is contraindicated during pregnancy and in women of childbearing potential not using contraception.

Breast feeding: Since it passes into the mother's milk, the use of thiocolchicoside is contraindicated during breastfeeding

Fertility: In a fertility study performed in rats, no impairment of fertility was seen at doses up to 12 mg/kg, i.e. at dose levels inducing no clinical effect. Thiocolchicoside and its metabolites exert aneugenic activity at different concentration levels, which is a risk factor for impairment of human fertility

PRECAUTIONS

Do not give this medicine to children and adolescents below 16

years old because of safety concerns. Reduce the dosage, as necessary, in case of diarrhea

Strictly respect the doses and duration of treatment. You should not use this medicine at higher dose or for longer than 7 days (for oral forms)/5 days (for IM forms). 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 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.

ADVERSE REACTIONS

Rare: Diarrhea, gastralgia, nausea, vomiting, drowsiness, cutaneous allergic reactions, angioedema

Very rare: Anaphylactic reactions, such as hypotension or anaphylactic shock with intramuscular administration.

DOSAGE AND ADMINISTRATION

Recommended dosage and duration of administration:

Two 4 mg capsules bid for 5 to 7 days.

Administration scheme

Severe muscular contracture:

The treatment will be initiated by the intramuscular route at the dosage of one 4 mg ampoule bid for 3 to 5 days, and eventually continued by the oral route at the dosage of two 4 mg capsules bid for 5 to 7 days.

Mild to moderate muscular contracture:

Two 4 mg capsules bid for 5 to 7 days.

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

OVERDOSAGE

No overdosage symptoms have been reported in patients treated with thiocolchicoside. Should overdosage occurs, medical supervision and symptomatic measures are recommended.

INSTRUCTIONS

Store below 30°C. Protect from heat, light and moisture. Keep all medicines out of the reach of children. To be sold on the prescription of a registered medical practitioner only.

PRESENTATION

Colchid (Thiocolchicoside) Capsules 4mg are available in Alu-PVC blister pack of 2x10's with leaf insert.

Manufactured for:

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ISO 9001:2015

ISO 14001:2015

ISO 45001:2018

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