

## Safety Alert

Dec 2024

### Thiocolchicoside and restrictions associated with the risk of genotoxicity

EDA performs label update to include the following:

#### Contraindications:

Thiocolchicoside should not be used in case of:

- **Pregnancy and breastfeeding**
- women of childbearing potential who are not using effective contraception during treatment with Thiocolchicoside Mylan Generics and for one month after stopping treatment men who are not available to use effective contraception during treatment with Thiocolchicoside Mylan Generics and for 3 months after stopping treatment

#### Special warnings and precautions for use

##### **Genotoxic potential**

Preclinical studies have shown that one of the metabolites of thiocolchicoside (SL59.0955), at concentrations close to human exposure, induces aneuploidy (i.e. an unequal number of chromosomes in dividing cells) at oral doses of 8 mg twice daily. Aneuploidy is considered a risk factor for teratogenicity, embryo/foetal toxicity, spontaneous abortion and reduced male fertility and a potential risk factor for tumors. As a precautionary measure, the use of the product at doses higher than recommended or long-term use should be avoided.

Patients (both male and female) should be carefully informed of the potential risks in case of pregnancy and on the effective contraceptive measures to be followed

##### **Background**

This medicine is a muscle relaxant. It is used in adults and adolescents over 16 years of age as an adjunctive treatment for painful muscle contractures. It should be used for acute conditions related to the spine.

#### **References:**

AIFA ( [Click here](#) )