

# HEALTHCARE PROFESSIONAL GUIDE for systemic use of thiocolchicoside

[Version dated November 2017]

## Adverse Event Reporting:

Any adverse events experienced by your patients should be reported to Sanofi India Ltd. Please find below the contact details for reporting adverse events:

Email: [PV.india@sanofi.com](mailto:PV.india@sanofi.com)

Toll free Telephone number: 1800 22 2295

Thiocolchicoside is indicated\* as **adjuvant treatment of painful muscle contractures in acute spinal pathology** in adults and adolescents from 16 years onwards.

Thiocolchicoside for systemic use should be strictly prescribed at **recommended doses**:

### For oral forms:

- Recommended and **maximal** dose is **8 mg every 12 hours** (i.e. 16 mg per day)
- Treatment duration **limited to 7 consecutive days**

### For IM form:

- Recommended and **maximal** dose is **4 mg every 12 hours** (i.e. 8 mg per day)
- Treatment duration **limited to 5 consecutive days**

*[Please refer to the Prescribing Information or complete information on indication and posology]*

*\*The revised restricted wording of the indication has been submitted to regulatory authorities and awaits their approval*

# Safety information to convey to patients

at time of prescription of Thiocolchicoside (for systemic use)

Risk of **genotoxicity** in animals which is a risk factor in humans for **teratogenicity, embryo/foeto toxicity, spontaneous abortion, impaired male fertility**, as well as a potential risk factor for **cancer** (as described in Prescribing Information).

Measures to be respected **prior prescribing thiocolchicoside** for preventing from this risk :

- **Maximal doses and short treatment duration** should be respected
- **Women of childbearing potential** should have **effective contraception**
- **Contraindication during pregnancy**
- **Contraindication during lactation**

Thiocolchicoside should be stopped if patient is **pregnant, might become pregnant or think may be pregnant** and patient should **consult a physician**

The health care professional should discuss with the patient the information pertaining to the risks associated with systemic use of thiocolchicoside, and **give her/him the patient card**

**Thiocolchicoside is contraindicated and must not be used:**

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

*[Please refer to the Prescribing Information for complete information on contraindications]*