Any adverse events experienced by your patients should be reported to the National Reporting System according to the National Regulation

Call for Reporting.
Healthcare professionals should report any adverse events suspected to be associated with the use of Coltramyl to Sanofi Malta Ltd., 3rd Floor, Avantech Building, St. Julian's Rd., San Gwann SGN 2805. Tel: 21493022, fax 21493024

Alternatively any suspected ADRs and medication errors can be reported to the Medicines Authority. Report forms can be downloaded from www.medicinesauthority.gov.mt/ adrportal and posted to Medicines Authority Post-Licensing Directorate, 203, Level 3, Rue D'Argens, Gzira GZR 1368, MALTA, or sent by email to postlicensing.medicinesauthority@gov.mt

Healthcare professional Guide for systemic use of Thiocolchicoside

[Version dated 18 February 2014]

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 4 mg and 8 mg forms: recommended and maximal dose is 8 mg every 12 hours (i.e. 16 mg per day) and treatment duration **is limited to 7 consecutive days.**
- For IM form: recommended and maximal dose is 4 mg every 12 hours (i.e. 8 mg per day) and treatment duration is **limited to 5 consecutive days**.
- For Both oral and IM forms: **doses exceeding recommended doses or long-term use should be avoided**.

[Please refer to the SmPC for complete information on indication and posology]

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Thiocolchicoside (for systemic use) contraindications and warnings

Thiocolchicoside is contraindicated and 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.**

[Please refer to the SmPC for complete information on contraindications]

Special warnings and precautions for use when using Thiocolchicoside

- **Preclinical studies showed that one of thiocolcoside 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/foeto-toxicity, spontaneous abortion, and impaired male fertility and a potential risk factor for cancer. As a precautionary measure, use of the product at doses exceeding the recommended dose or long-term use should be avoided.**

[Please refer to the SmPC for complete information on warnings and non-clinical findings]

Safety information to convey to patients at time of first prescription of thiocolchicoside (for systemic use)

The prescriber/HCP should discuss with the patient the information pertaining to the risks associated with systemic use of thiocolchicoside, and give her/him the patient card

Please counsel your patients regarding the following:

- **Risk of teratogenicity of thiocolchicoside in animals and its possible teratogenic effects in humans** (as described in SmPC)
- **Measures to be taken for preventing from this risk** prior taking thiocolchocoside (for systemic use):
  - **Recommended doses and treatment duration should not be exceeded**
  - **Thiocolchicoside is contraindicated during pregnancy and lactation and woman of childbearing potential should have adequate contraception**
  - **Thus** thiocolchocoside should be stopped if patient is **pregnant, might become pregnant or think may be pregnant, and patient should consult a physician**