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

Reporting suspected adverse reactions after authorisation of the medicinal product is important. Healthcare professionals are reminded to continue to report suspected adverse reactions associated with fluoroquinolones medicines in accordance with the national spontaneous reporting system. Any suspected adverse reactions and medication errors can be reported via the national Adverse Drug Reactions (ADRs) reporting system.

Report forms can be downloaded from www.medicinesauthority.gov.mt/adrportal and posted to Post-licensing directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000, Malta or sent by email to postlicensing.medicinesauthority@gov.mt

HEALTHCARE PROFESSIONAL GUIDE for systemic use of thiocolchicoside

[Version dated November 2018]

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information.

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 SmPC for complete information on indication and posology]

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 SmPC).*

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 SmPC for complete information on contraindications]