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

# Patient Card for thiocolchicoside (for systemic use)

Thiocolchicoside is a muscle relaxant. Under its systemic forms (oral tablets/capsules or intramuscular injection), it is **used in adults and adolescents from 16 years onwards as an adjuvant treatment for painful muscular contractions**. It is to be used for acute conditions related to spinal column.

Before taking Thiocolchicoside (for systemic use) you should be informed that:
One of the products formed in your body when taking thiocolchicoside has shown to cause **damage to some cells (abnormal number of chromosomes)** in animals and in cell laboratory studies. **In humans, this type of damage to cells is a risk factor for harm to the unborn child and impairment of male fertility and a potential risk factor for cancer**.

**Always take this medicine exactly as your doctor or pharmacist has told you.**

**You MUST NOT TAKE** Thiocolchicoside (for systemic use) **if:**

- ☐ You are pregnant or think you may be pregnant
- ☐ You are breast-feeding
- ☐ You are a woman of childbearing potential not using efficient contraception

**Do not exceed the recommended doses and treatment duration, which are, respectively:**

- **8 mg every 12 hours** (i.e. 16 mg per day) for the **oral form** 4 mg and 8 mg **limited to 7 consecutive days**.
- **4 mg every 12 hours** (i.e. 8 mg per day) for **intramuscular form limited to 5 consecutive days**.

**Contact your doctor:**

- ☐ Immediately upon suspicion of pregnancy

**If you get any side effects**, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet.

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

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