

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.

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, Gżira GŻR 1368, MALTA, or sent by email to postlicensing.medicinesauthority@gov.mt