For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

Abridged Prescribing Information

MYORIL®

THERAPEUTIC CATEGORY
Antispasmodic

COMPOSITION:
MYORIL® Capsules 4mg: Each hard gelatin capsule contains Thiocolchicoside I.P. 4 mg
MYORIL® Capsules 8 mg: Each hard gelatin capsule contains Thiocolchicoside I.P. 8 mg
MYORIL® Injection 4mg / 2ml: Each 2ml ampoule contains Thiocolchicoside I.P. 4 mg

THERAPEUTIC INDICATIONS: As an adjuvant treatment in painful spasm associated with degenerative vertebral disorders and vertebral static problem, torticollis, dorsal pain, low back pain, traumatological and neurological disorders.

DOSAGE AND ADMINISTRATION: Oral route: The recommended and maximal dose is 8 mg every 12 hours (i.e. 16 mg per day). The treatment duration is limited to 7 consecutive days. Intramuscular route: The recommended and maximal dose is 4 mg every 12 hours (i.e. 8 mg per day). The treatment duration is limited to 5 consecutive days.
Doses exceeding recommended doses or long-term use should be avoided (see Warnings).
Not recommended for use in children below the age of 16 years.

SAFETY RELATED INFORMATION
CONTRAINDICATIONS: Hypersensitivity to thiocolchicoside or one of its excipients; pregnancy and lactation; in women of child bearing potential not using effective contraceptive.

WARNINGS: In preclinical studies, one of thiocolchicoside metabolites (SL59.0955) induced aneuploidy at concentrations close to human exposure observed at doses 8 mg twice daily *per os.* Aneuploidy is reported as a risk factor for teratogenicity, embryofoetotoxicity/spontaneous abortion, cancer, and impaired male fertility. As a precautionary measure, use of the product at doses exceeding the recommended dose or long term use should be avoided.

Postmarketing cases of cytolytic and cholestatic hepatitis have been reported. Severe cases in patients concomitantly taking NSAIDs or paracetamol. Patients should be advised to stop treatment and report any sign of liver toxicity. Thiocolchicoside may precipitate seizures, especially in patients with epilepsy or those at risk for seizures. Patients should be carefully informed about the potential risk of a possible pregnancy and about effective contraceptive measures to be followed. *For Myoril Capsules:* Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

PRECAUTIONS:
In case of diarrhea, the treatment with thiocolchicoside should be stopped.
Myoril Injection only: Cases of syncope vasovagal have been observed and therefore the patient should be monitored after the injection (see Adverse reactions)

PREGNANCY AND LACTATION
The use of thiocolchicoside is contraindicated in pregnancy and in women of child bearing potential who are not using effective contraceptive.Contraindicated during breast feeding.

DRIVING A VEHICLE OR PERFORMING OTHER HAZARDOUS TASKS
There is no data available on the effect on driving vehicles and using machines. Somnolence may occur commonly and that has to be taken into account when driving vehicles and operating machines.

ADVERSE REACTIONS: Very common (≥ 10%) and common (≥1 and <10%) adverse reactions are somnolence, diarrhoea, gastralgia.

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Source: CCDS V: 5.0 dated April 2016

For full prescribing information please write to : Sanofi-Synthelabo (India) Pvt. Ltd., Sanofi House, CT Survey No. 117-B, L&T Business Park, Saki Vihar Road, Powai, Andheri – 400 072, Tel: 022 28032000