MYORIL® CAPSULE/ INJECTION Abridged Prescribing Information

COMPOSITION:
Thiocolchicoside I.P.
MYORIL® CAPSULE 4 mg: Each hard gelatin capsule contains Thiocolchicoside I.P. 4 mg
MYORIL® CAPSULE 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

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: In case of severe muscular contracture: One 4mg ampoule bid for 3 to 5 days, eventually continued by oral route at the dosage of two 4mg capsules bid for 5 to 7 days. In case of mild to moderate muscular contracture: Two 4mg capsules bid or 8mg capsule bid for 5 to 7 days.

CONTRAINDICATIONS: Hypersensitivity to thiocolchicoside or one of its excipients; Pregnancy and lactation.

WARNINGS: Applies to the oral form only: Patients with rare hereditary problems of galactose and fructose intolerance should not take this medicine.

PRECAUTIONS: Thiocolchicoside may precipitate seizures in patients with epilepsy or those at risk for seizures.
Applies to the oral form only: Reduce the dosage as necessary in case of diarrhea.
Applies to the IM form only: Due to cases of syncope vasovagal, the patient should be monitored after the injection
Not recommended for use in children below the age of 15 years.

UNDESIRABLE EFFECTS: Cases of anaphylactic reactions, such as pruritus, urticaria, angioneurotic oedema; anaphylactic shock following intramuscular injection, somnolence, syncope vasovagal, usually occurring in the minutes following the IM injection, diarrhoea, gastralgia, nausea, vomiting and allergic skin reaction.

For full prescribing information please write to: Sanofi-Synthelabo (India) Limited, A Sanofi Group Company, 54/A, Sir Mathuradas Vasanji Road, Andheri (East), Mumbai – 400093

Created: December 2009