

Thiamine Mononitrate/Thiamine Hydrochloride USP, Pyridoxine Hydrochloride USP and Cvanocobalamin USP Film Coated Tablet/Injection

DESCRIPTION

Solbion® is a preparation of Thiamine Mononitrate/Thiamine Hydrochloride (Vitamin B_1) USP, Pyridoxine Hydrochloride (Vitamin B_6) USP and Cyanocobalamin (Vitamin B_{12}) USP. It is a combination of three water-soluble vitamins in an acceptable tablet/injectable formulation. It is formulated as a prophylactic or therapeutic nutritional supplement and it is indispensable for a normal course of nervous metabolism.

INDICATIONS

Solbion® is indicated where a deficiency of the relevant vitamins exists. It is also indicated for the treatment of:

• Chronic painful conditions like- Lumbago, sciatica, myalgia etc. • Nociceptive pain due to fractures, burns, sprains, bruises etc. • Different neuralgia (e.g. peripheral neuralgia, facial neuralgia, intercostal neuralgia etc.) • Diabetic neuropathy

DOSAGE AND ADMINISTRATION

Solbion® may be administered in a dosage of 1-3 tablets daily or as directed by the registered physician. **Solbion®** IM Injection is injected intramuscularly (deep intragluteal). In severe cases, 1 ampoule daily until the acute symptoms subside. For milder cases and follow-up therapy, 2 or 3 ampoules per week.

CONTRAINDICATIONS

Combination of vitamin B_1 , B_6 and B_{12} is contraindicated in the individual known to be hypersensitive to any of its ingredients and patients on levodopa therapy.

SIDE-EFFECTS

Generally well tolerated. However a few allergic reactions may be seen during treatment.

WARNING

Cyanocobalamin should not be given before a diagnosis has been fully established because of the possibility of masking symptoms of subacute degeneration of the spinal cord.

Cyanocobalamin is not a suitable form of Vitamin B_{12} for the treatment of optic neuropathies associated with raised plasma concentrations of cyanocobalamin.

USE IN PREGNANCY AND LACTATION

Solbion® can be used in pregnancy and lactation.

DRUG INTERACTION

Concomitant use of the combination of vitamin B₁, B₆ and B₁₂ with levodopa may decrease the efficacy of levodopa.

PHARMACEUTICAL PRECAUTIONS

Solbion® Tablet: Do not store above 30 °C. Keep away from light and wet place. Keep out of reach of children. **Solbion® IM Injection:** Store in a refrigerator (2 °C-8 °C). Keep away from light. Keep out of reach of children.

PACKAGING

Solbion® Tablet:

Box containing 5 strips of 10 tablets each. Each film coated tablet contains Thiamine Mononitrate (Vitamin B_1) USP 100 mg, Pyridoxine Hydrochloride (Vitamin B_6) USP 200 mg and Cyanocobalamin (Vitamin B_{12}) USP 200 mcg.

Solbion® IM Injection:

Box containing 10 ampoules each. Each ampoule (3 mL) contains Thiamine Hydrochloride (Vitamin B_1) USP 100 mg, Pyridoxine Hydrochloride (Vitamin B_6) USP 100 mg and Cyanocobalamin (Vitamin B_{12}) USP 1 mg.



Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

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