

Prescribing Information (Summary of Product Characteristics)

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

Vitamin B-Complex Injection, 10 mL

1.1 PRODUCT NAME

Swiss Vita

1.1 STRENGTH

10 mL

1.2 PHARMACEUTICAL FORM

Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

2.1 QUALITATIVE DECLARATION

Each ml contains:

Vitamin B1 BP, Vitamin B2 BP, Vitamin B6 BP, Nicotinamide BP,

Dexpanthenol USP

Benzyl Alcohol BP.....0.2% v/v (As preservative)

3. PHARMACEUTICAL FORM

Solution for Injection

Description: A Clear Yellow colour solution free from visible Particles and fibres

4. CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Indication:

Vitamin B complex injection is usually well tolerated. It must be injected slowly. In disorders requiring parenteral administration of vitamins, i.e., pre- and post-operative treatment, when requirements are increased as in fever, severe burns, increased metabolism, pregnancy, gastrointestinal disorders interfering with intake or absorption of vitamins, prolonged or wasting diseases, alcoholism and where other deficiencies exist.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

Usually, 0.25 to 2 mL by intramuscular or slow intravenous injection. High concentrations given intravenously may be diluted using parenteral infusion solutions.

Deficiency can be reversed by thiamine in doses as small as 500 micrograms daily.

A therapeutic dose of 1 to 2 mL daily is recommended.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever the solution and container permit.

Method of administration:

Vitamin B Complex Injection is administered by Intramuscular or Intravenous injection.

4.3 CONTRAINDICATIONS

Vitamin B complex should not be used in hypersensitivity to any of the vitamins, containing in the preparation, as well as in patients with 2nd or 3rd degree arterial hypertension.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Because of in vitro incompatibility the preparation should not be used simultaneously (in the same syringe) with following preparations: Benzylpenicillin and oxacyllin (the antibiotic precipitates and is inactivated), macrolides (insoluble sedimentation is formed); Chloramphenicol (precipitation); Vitamin B12 (cobalt ions destruct vitamin B2); Vitamin C (inactivates vitamin B6).

Vitamin B complex injection is usually well tolerated. It must be injected slowly.

Anaphylactogenesis may occur with parenteral thiamine. Use with caution. An intradermal test dose is recommended prior to administration in patients suspected of being sensitive to the drug.

Precautions:

The usual precautions for parenteral administration should be observed. Do not inject if precipitate occurs. Inject slowly by the intravenous route. High concentrations should be diluted using Normal Saline Injection when giving intravenously.

Warning for Benzyl Alcohol: Do not use this medication on an infant younger than 6 months old. Benzyl alcohol topical contains an ingredient that can cause serious side effects or death in very young or premature babies. Tell your healthcare provider if your baby was born prematurely.

4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER

FORMS OF INTERACTION

The preparation may reduce the antihypertensive effect of some adrenoreceptor blockers and adrenolytics, as well as to decrease the hypnotic effect of barbiturates and glutethimide, due to vitamin B1 persistence. Chlorpromazine increases the urine excretion of the vitamin B2. Probenecid inhibits tubular excretion and reabsorption of the vitamin B2, reducing its excretion in urine. Vitamin B6 reduces the antiparkinsonic effect of L-Dopa. In concomitant treatment with oral contraceptive agents, isoniazid, penicillamine, cicloserin, and thiosemicarbazones the blood concentration of vitamin B6 is reduced

4.6 PREGNANCY AND LACTATION

The preparation could be used in pregnant and nursing women when really needed.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Not Applicable

4.8 UNDESIRABLE EFFECTS

Mild transient diarrhea, polycythemia vera, peripheral vascular thrombosis, itching transitory exanthema, feeling of swelling of entire body, anaphylactic shock and death. Sensitivity to the ingredients listed may occur. Use should be discontinued upon observance of any untoward reaction. Pain upon intramuscular injection may be noted.

4.9 OVERDOSE

Thiamine Hydrochloride: can lead to skin rash, insomnia, palpitation of heart, hypertension, and patient feels agitated. Parenteral route (injection) can sometime cause anaphylactic shock.

Riboflavin: Nausea, vomiting, tiredness, low blood pressure.

Nicotinamide: consuming excess of nicotinamide can lead to a characteristic flush especially on the face, which may burn and become red. It can also alter the liver function resulting in jaundice. Headache, joint pain, high blood sugar, acidity, nausea and muscle cramps.

Dexpanthenol: depression, dehydration, swelling in legs and face due to water retention, tiredness, and pain in knee and other joints, acidity, nausea, vomiting and diarrhea.

Pyridoxine Hydrochloride: tingling and numbness in extremities due to nerve damage, pain in legs and hands having no known etiology. All this symptoms are related to

sensory peripheral neuropathy. Neonates may suffer from hypoxaemia. Decrease in estrogen and prolactin level.

5. PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMICS PROPERTIES

Riboflavin is bound to plasma proteins. A little is stored in organs such as liver and kidneys, and amounts in excess of the body's requirements are excreted in the urine.

Thiamine is fundamentally associated with carbohydrate metabolism.

By combining with the pyrophosphoric acid in nucleated cells, particularly in the liver, kidneys and white blood cells it is converted in the body to its pyrophosphate which acts as coenzyme in such reactions as the decarboxylation of alpha-keto acids, particularly of pyruvate and alpha-keto-glutarate. In the presence of thiamine deficiency pyruvic and lactic acids accumulate in the tissues.

6. PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Benzyl Alcohol BP

Disodium EDTA BP

Propyleneglycol BP

Sodium Hydroxide BP

Water for Injection BP

6.2 INCOMPATIBILITIES

Not Applicable

6.3 SHELF-LIFE

Vitamin B-Complex Injection 10 ml, has a shelf life of 3 years.

In use Shelf life: Use within 30 days of first opening.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 30°C. Protect from light. Keep out of reach of children

6.5 NATURE AND CONTENTS OF CONTAINER

Available in an Amber glass vial

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER

Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Swiss Parenterals Limited.

808, 809, & 810 Kerala Industrial Estate, G.I.D.C,

Nr, Bavla, Dist. Ahmedabad-382 220.

Gujarat, India.

8. MARKETING AUTHORISATION NUMBER

TAN 21 HM 0385

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

2021-10-09

10. DATE OF REVISION / APPROVAL OF THE TEXT