

**SKM PHARMA PVT LTD**

TF 10, City Point, Infantry Road, Bangalore 560001, INDIA  
+919880039682 Email: skmpharmabl@gmail.com



Document Name	<b>SUMMARY OF PRODUCT CHARACTERISTICS – VISCOPLEX FORTE INJECTION</b>		
Document No	<b>C/SMPC/21/001</b>	EFFECTIVE DATE	<b>25/02/2022</b>

**SUMMARY OF PRODUCT**  
**CHARACTERISTICS**

**VISCOPLEX FORTE INJECTION**

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**1. NAME OF THE MEDICINAL PRODUCT:**

VISCOPLEX FORTE INJECTION (Vitamin B-complex Injection)

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION:**

Composition:

**Each 10 ml vial contains:**

Vitamin B1	B.P.	25.00 mg
Vitamin B2	B.P.	2.00 mg
Vitamin B6	B.P.	2.50 mg
Nicotinamide	B.P.	50.00 mg
D-Panthenol	B.P.	5.00 mg
Benzyl Alcohol	B.P.	2% w/v

**3. PHARMACEUTICAL FORM**

Injection

A clear yellow coloured solution

**4. CLINICAL PARTICULARS****4.1 THERAPEUTIC INDICATIONS**

Vitamin B-complex injection is a dietary supplement where the dietary intake is inadequate or in pronounced deficiency state. As a prophylactic supplement for infants, children, pregnant women and nursing mothers.

In defined cases of clinical deficiency, parenteral administration is recommended for quick recovery of health and wellbeing.

In mild to moderate deficiency of Vitamin B-complex where parenteral use is recommended. Convulsions, pregnancy and lactation adjuvant therapy with antibiotic supportive therapy for cardiac and diabetic patients, post-operative treatment.

**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.

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.

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**Method of administration:**

Vitamin B-complex injection is administered by very slow I.V. or Intravenous injection.

**4.3 CONTRAINDICATIONS:**

No known contraindications have been indicated so far for the use of B-complex vitamins. However, a few persons are hypersensitive to any of the vitamins containing in the preparation, as well as in patients with 2<sup>nd</sup> or 3<sup>rd</sup> degree arterial hypertension.

**4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE**

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

Special care should be taken of patients with known allergic disposition.

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

**Precautions:**

The usual precaution 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 given intravenously.

**4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION**

Drug interactions with vitamins are rare and have not been reported. In fact, they are given as nutritional supplement during drugs therapy especially when treating with antibiotics. During treatment with isoniazid, a deficiency state of Vitamin B6 may occur and hence this vitamin is given during the period.

**4.6 FERTILITY, PREGNANCY AND LACTATION**

Not known

**4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES**

Not known

**4.8 UNDESIRABLE EFFECTS**

Rarely, hypersensitivity reactions to Vitamin B1 may occur following parenteral administration of VISCOPLEX FORTE INJECTION leading to skin rash, itching or even anaphylaxis involving nausea, vomiting, bronchospasm and circulatory collapse.

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#### 4.9 OVERDOSE

Generally, B-complex vitamins are good for health. As a result of different parts of the complex vitamin or overdose of Vitamin B-complex following side effects may occur.

- Black stools
- Constipation
- Abdominal pain
- Vomit
- Nausea
- Frequent urination
- Changes in urine color
- Diarrhea
- Itching
- Redness of skin

In rare cases allergic reactions could also happen including itchiness and rashes. If you experience persisting side effects call your doctor.

#### 5.0 PHARMACOLOGICAL PROPERTIES

##### 5.1 PHARMACODYNAMIC PROPERTIES

###### Vitamin B1 – Thiamine

Thiamine functions in all cell as the coenzyme cocarboxylase (thiamine pyrophosphate). It is the coenzyme for all enzymic decarboxylations of  $\alpha$ -ketoacids. There are several other metabolic processes in which thiamine plays an essential role. Because its principle functions are concerned in energy metabolism, its requirement by the body bears a direct relation to the energy intake.

Thiamine is a cofactor in the metabolism of carbohydrate. This function is particularly important in nerve cell function. It also potentiates and mimics the effects of acetylcholine in the brain. These attributes explain its use in Alzheimer's disease, being senescent forgetfulness and in epileptics taking Dilantin.

###### Vitamin B2 – Riboflavin-5-phosphate

Vitamin B2, also known as Riboflavin, is an easily absorbed, water soluble micro nutrient with a key role in maintaining human health. Like the other B vitamins, riboflavin supports energy production by aiding in the metabolization of fats, carbohydrates and proteins.

Vitamin B2 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. Helps cells produce energy. It is also required for the growth and for health of skin and mucous membranes, as well as vision.

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**Vitamin B6 – Pyridoxine**

Vitamin B6 is an essential part of protein and amino acid metabolism, and in the formation of new proteins including haemoglobin. It is critical to nervous function and vision, maintains skin integrity and is involved in red blood cell formation.

**Vitamin B3 –Nicotinamide**

Vitamin B3 help the digestive system, skin and nerves to function properly

**D-Panthenol (Provitamin B5)**

Provitamin B5 is essential nutrient needed for healthy skin, hair and liver

The B-complex vitamins are intimately involved with red blood cell formation. They are all closely dependant on each other, so the absence of one will critically effect the activity of all others. As water soluble vitamin, they need to be taken in on a daily basis, and they are equally rapidly excreted, so B-complex vitamins must be supplemented on a regular basis.

The importance of B-complex vitamins cannot be understated. Vitamin and minerals are usually required by the human body in extremely small quantities. However, the absence of that small quantity is likely to cause serious health problems to the individual.

**5.2 PHARMACOKINETIC PROPERTIES****Thiamine**

Vitamin B1 is readily absorbed from the small and large intestine. It can be administered parenterally.

Vitamin B1 is stored in the body. It is mainly concentrated in the liver, muscles, heart, kidneys and brain. The stores can be considerably reduced in a few days and so vitamin B1 should be administered during acute illness when the food intake is poor.

Vitamin B1 is excreted in the urine, and a little is present in the faeces, though how much of this is the result of bacteriosynthesis in the intestines is not known.

**Riboflavin:**

Riboflavin is absorbed from the intestines. It is also absorbed when given parenterally.

Riboflavin is excreted in the urine and milk. Excess in the body is rapidly excreted in the urine to which it imparts a yellow color.

**Nicotinamide:**

Nicotinamide is rapidly absorbed from the stomach, the small and the large intestine. As an essential tissue coenzyme, nicotinamide is distributed in cells throughout the body.

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**Pyridoxine:****Absorption:**

The absorptions of Vitamin B6 from the intestine is rapid and occur by diffusion mainly from the jejunum. It is also absorbed from the skin. If applied over a large area of skin, enough is absorbed to relieve all clinical and chemical signs of B6 deficiency.

The storage of Vitamin B6 in the body is usually sufficient to last for about 8 weeks.

All three components of Vitamin B6 are found in the urine after ingestion but 4-pyridoxic acid is quantitatively the most important excretion product. On a vitamin B6 deficient diet, the excretion can be higher than the intake.

**5.3 PRECLINICAL SAFETY DATA**

Not known

**6.0 PHARMACEUTICAL PARTICULARS****6.1 LIST OF EXCIPIENTS**

- Benzyl Alcohol I.P. (Preservative)
- Disodium EDTA I.P. (Chelating Agent)
- Sodium Acid Phosphate I.P. (Buffering Agent)
- Monothioglycerol 90% solution I.P. (Stabilizer)
- DL Methionine I.P. (Chelating Agent)
- Hydrochloric Acid I.P. (Buffering Agent)
- Water for injection I.P. (Preservative)

**6.2 INCOMPATIBILITIES**

None

**6.3 SHELF LIFE:**

24 months from the date of manufacturing

In use shelf life: use within 30 days of first opening

**6.4 SPECIAL PRECAUTIONS FOR STORAGE**

Store below 30°C, protected from direct light. Keep out of reach of children

**6.5 NATURE AND CONTENTS OF CONTAINER:**

In 10 ml Type III amber vial sealed with plug and aluminium seal

**6.6 SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING**

No special requirements

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**7. MARKETING AUTHORISATION HOLDER**

NANDO PHARMACY LIMITED  
51 OLD MARKET ROAD  
ONITSHA, ANAMBRA STATE  
NIGERIA 430003

**8. MARKETING AUTHORISATION NUMBER(S)**

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**9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION;**

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**10. DATE OF REVISION OF THE TEXT:**

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