1.3.1 Summary of Product Characteristics (SmPC)

**a. Product Details:**

CO-VITAMIN B INJECTION

Each ampoule (2ml) contains:

Vitamin B1 ……. 10mg

Vitamin B2 ……. 1.37mg

Vitamin B6 ……. 1mg

Nicotinamide …….. 15mg

Excipient…… ……..Q.S.

**Dosage form**: Injection

**Strength(s):**

Vitamin B1 ……. 20mg

Vitamin B2 ……. 2mg

Vitamin B6 ……. 2mg

**Route of administration:** i.v. / i.m.

**Pharmacopoeial Status API:**

Co-Vitamin B BP

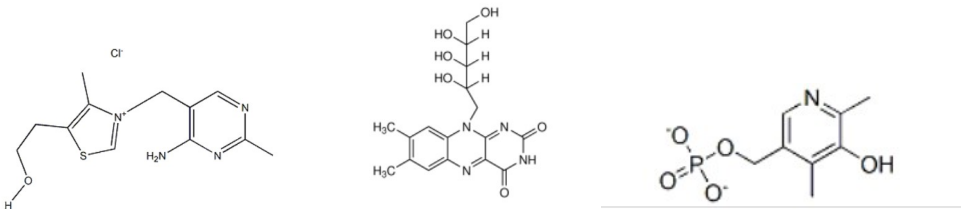
**Pharmacopoeial status FP:** CP 2010

**b. Component of the drug product**

**Active Ingredients**

**MC FORIS** is an injection. It is used for the treatment and prevention of Co-Vitamin B deficiency. It is essential to identify the exact cause of deficiency, preferably before starting therapy. Hydroxocobalamin is generally preferred to cyanocobalamin; it binds more firmly to plasma proteins and is retained in the body longer. Cyanocobalamin and hydroxocobalamin are generally given by the intramuscular route, although cyanocobalamin may be given by mouth or intranasally. Oral cyanocobalamin may be used in treating or preventing Co-Vitamin B deficiency of dietary origin.

**Structure:**



**Physicochemical Characteristics:**

**Description :**

A white or almost white, crystalline powder or colourless crystals.

**Solubility:** Sparingly soluble in water and in alcohol; practically insoluble in acetone.

**Excipients:**

**(1) Sodium Chloride**

**Functional Category:**

As a cosolvent.

**Applications in Pharmaceutical Formulation or Technology**

The concentration and dosage of sodium chloride solutions for intravenous use is determined by several factors including the age, weight, and clinical condition of the patient and in particular the patients' hydration state. Serum-electrolyte concentrations should be carefully monitored. In severe sodium depletion, 2 to 3 litres of sodium chloride 0.9% may be given over 2 to 3 hours and thereafter at a slower rate.

**Structural Formula:**

**NA + CL-**

**Description:** A white, crystalline powder or colourless crystals or white pearls.

**Solubility:** Freely soluble in water; practically insoluble in dehydrated alcohol.

**(2) Water For Injection**

**Functional Category:**

As a solvent for injection.

**Applications in Pharmaceutical Formulation or Technology**

It is water for the preparation of medicines for parenteral administration when water is used as the vehicle, and for dissolving or diluting substances or preparations for parenteral administration. It is prepared by distillation of potable water or purified water from a neutral glass, quartz, or suitable metal still fitted with an effective device for preventing the entrainment of droplets; the first portion of the distillate is discarded and the remainder collected. Store in conditions designed to prevent growth of micro-organisms and to avoid any other contamination.

**Description:** A clear colourless liquid.

### 1.3.2 Labelling (outer & inner labels)

Will be submitted later

1.3.3 Package Insert (also known as patient information PIL)

# PATIENT INFORMATION LEAFLET

## PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

## Co-Vitamin B Injection (MC FORIS)

复合Vb说明书 正反面 成品100x170mm 黑一色

## VITAMIN B COMPLEX INJECTION

**COMPOSITION:**

Each 2ml amp. contains:

Thiamine Hydrochloride ..... 20mg
Riboflavine ..... 2mg
Pyridoxine Hydrochloride ..... 2mg
Nicotinamide ..... 50mg
Calcium Dextropantothenate ..... 1mg

**CHEMISTRY:**

Thiamine Hydrochloride is 3-[(4-amino-2-methylpyrimidin-5-yl) methyl]-5-(2-hydroxyethyl)-4-methylthiazolium chloride hydrochloride.

Riboflavin Sodium phosphate is the dehydrate of the monosodium salt of 3,10-dihydro-7,8-dimethyl-10-[(2S,3S,4R)-2,3,4-trihydroxypentyl]-benzopteridine-2,4-dione-5' -phosphate.

Pyridoxine Hydrochloride is 5-hydroxy-6-methylpyridine-3,4-dimethanol hydrochloride.

Nicotinamide is pyridine-3-carboxamide.

Sodium Pantothenate is calcium Sodium(R)-N-(2,4-dihydroxy-3,3-dimethyl-1-oxobutyl)-B-alaninate

包装确认，胡领军

**INDICATIONS:**

Thiamine is an essential coenzyme for carbohydrate metabolism.Thiamine deficiency develops when the dietary intake is inadequate;severe deficiency leads to the development of a syndrome known as beri-beri.Chronic 'dry' beri-beri is characterized by peripheral neuritis,bradycardia muscle weakness and paralysis.Acut 'wet' beri-beri is characterized by cardiac failure and oedema.Demyelination of the central nervous systen may develop in severe cases of thiamine deficiency.

Riboflavin is essential for the utilisation of energy from food. The active flavine mononucleotide and flavine adenine dinucleotide are involved as coenzymes in oxidative/reductive metabolic reaction.Riboflavin deficiency develops when the dietary intake is inadequate.Deficiency leads to the development of a well-defined syndrome known as ariboflavinosis, characterized by cheilosis,angular stomatitis, glossitis and seborrhoeic keratosis of the nose and anogenital region. There may also be ocular symptoms including itching and burning of the eyes, photophobia and corneal vascularisation.

Pyridoxine is involved principally in amino acid metabolism, but is also involved in carbohydrate and fat metabolism.It is also required for the formation of haemoglobin.Pyridoxine deficiency in adults leads to the development of peripheral neuritis, deficiency in children also affects the CNS. It is used in the treatment of sideroblastic enemies, in certain metabolic disorders.

Nicotinamide and Nicotinic acid occurs naturally in the body are vitamin B substances,which are converted to nicotinamide adenine dinucleotide(NAD)and nicotinamide adenine dinucloctide phosphate(NADP).These coenzymes are involved in electron transfer reaction in the respiratory chain.Nicotinamide and Nicotinic acid are used in the treatment and prevention of nicotinic acid deficieney.Its deficieney develops when the dietary intake is inadequate.Deficiency leds to the development of the syndrome known as pellagra,characterized by skin lesion, especially on areas exposed to sunlight, with hyperpigmentation and hyperkeratinisition.Other symptoms include diarrhoea, abdominal pain, glossitis, stomatitis, loss of appetite, headache, lethargy, and mental and neurological disturbances.

Dexpanthenol is the alcoholic analogue of D-Pantothenic acid and is considered to be a vitamin B substance.It has been used in a variety of conditions including control gastro-intestinal atony.

**CONTRA-INDICATIONS:**

It is contra-indicated in haemophiliacs and in patients with ileus due to mechanical obstruction.

**ADVERSE EFFECTS:**

Rarely hypersensitivity reactions or allergy and other side effects are associated with long term administration of large doses.

**ADMINISTRATION:**

It may be given by intramuscular or intravenous injection in dose of 2ml or mono daily for adults. Or in a dose decided by a registered medical practitioner only.

**AVAILABILITY:**

Ampoules of 2ml-box of 10 ampoules.
Ampoules of 2ml-box of 100 ampoules.

MANUFACTURED FOR:
MC Foris Pharmaceuticals Ltd
ADD: 21, IBEZIM OBIAJULU STREET, MASHA
SURULERE, LAGOS STATE, NIGERIA.
MANUFACTURER LICENSE NUMBER:20160066