

1. Name of the medicinal product  
EM-B-PLEX

2. Qualitative and quantitative composition  
Each 5ml contains

Thiamine Hydrochloride	5.00 mg
Riboflavin Sodium	2.74 mg
Phosphate	20.00 mg
Nicotinamide	2.00 mg
Pyridoxine Hydrochloride	3.00 mg
Dexpanthenol	

3. Pharmaceutical form  
Oral Solution

4. Clinical particulars

4.1 Therapeutic indications

Oral prophylactic and therapeutic treatment of vitamin B complex deficiency.

4.2 Posology and method of administration

Prophylactic

Children

up to 1 year, One 5ml spoonful daily

up to 12 years, One 5ml spoonful twice daily

Adults and elderly

One 5ml spoonful three times daily

Therapeutic

Children

up to 1 year, One 5ml spoonful three times daily

up to 12 years, Two 5ml spoonfuls three times daily

Adults and elderly

Two to three 5ml spoonfuls three times daily

Or as prescribed by a doctor

4.3 Contraindications

Known sensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

No special warnings.

4.5 Interaction with other medicinal products and other forms of interaction  
The pyridoxine hydrochloride may reduce the effectiveness of levodopa.

4.6 Pregnancy and lactation  
Considered safe in the recommended dose.

4.7 Effects on ability to drive and use machines  
None stated

4.8 Undesirable effects  
None known

### **Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme, Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

4.9 Overdose  
Not applicable.

5. Pharmacological properties  
5.1 Pharmacodynamic properties  
Vitamin B Complex.

***Thiamine Hydrochloride (Vit B1):*** A water soluble vitamin. It is a co-enzyme for carbohydrate metabolism.

***Riboflavine Sodium Phosphate (Vit B2):*** A water soluble vitamin converted in the body to flavine mononucleotide and flavine adenine dinucleotide and then involved as co-enzymes in oxidative and reductive metabolic processes.

***Nicotinamide:*** A water soluble vitamin considered part of the Vitamin B group. Converted to Nicotinamide Adenine Dinucleotide and Nicotinamide Adenine Dinucleotide Phosphate in the body, both of which are co-enzymes important in electron transfer in respiratory reactions.

***Pyridoxine Hydrochloride (Vit B6):*** A water soluble vitamin. Involved in carbohydrate and fat metabolism, but also important in haemoglobin formation.

***Pantothenol:*** The alcoholic analogue of D-pantothenic acid traditionally considered a B vitamin. It is a component of co-enzyme A, which is important in the metabolism of fat, carbohydrate and protein.

## 5.2 Pharmacokinetic properties

All the actives are water soluble vitamins. Quantities in excess of the bodies requirements are excreted either unchanged or as metabolites, mainly in the urine but to a lesser extent also in the faeces.

## 5.3 Preclinical safety data

None stated

## 6. Pharmaceutical particulars

### 6.1 List of excipients

Butyl Hydroxybenzoate, Disodium Edetate, Dilute Hydrochloric Acid, Ethyl Hydroxybenzoate, Methyl Hydroxybenzoate, Propyl Hydroxybenzoate, Propylene Glycol, Soluble Orange Oil Flavour, Sorbitol Solution 70% (non-crystallising), Purified Water

### 6.2 Incompatibilities

None known

### 6.3 Shelf life

36 months.

### 6.4 Special precautions for storage

Store between 4°C and 25°C. Protect from light.

### 6.5 Nature and contents of container

150ml Glass bottle.

Cap White PP28 TE CR with EPE/PE/AL/PET Wad

### 6.6 Special precautions for disposal and other handling

None stated

## 7. Marketing authorisation holder

Emzor Pharmaceutical Industries Limited

No 10, Kolawole, Shonibare Street,  
Ajao Estate, Isolo, Lagos Nigeria.

## 8. Marketing authorisation number(s)

NA

## 9. Date of first authorisation/renewal of the authorisation

NA

10. Date of revision of th  
NA