

# **SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)**

**1. NAME OF THE MEDICINAL PRODUCT**

Afrablex Syrup

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each 5ml contains:

Vitamin B1 (Thiamine HCl)	5mg
Vitamin B2 (Riboflavin 5-Phosphate)	2mg
Vitamin B6 (Pyridoxine HCl)	2mg
Vitamin B3 (Nicotinamide)	20mg

{For a full list of excipients, see section 6.1}

**3. PHARMACEUTICAL FORM**

Yellow syrupy liquid with a characteristic sweet taste

**4. Clinical particulars**

**4.1 Therapeutic indications**

- Prevention and treatment of Vitamin B complex deficiency.

**4.2 Posology and method of administration**

Posology

*Prophylactic (i.e. the prevention of Vitamin B complex deficiency).*

Children up to 1 year: 5ml to be taken daily.

Children 1 to 12 years: 5ml to be taken twice daily.

Adults: 5ml to be taken three times daily.

*Therapeutic (i.e. the treatment of Vitamin B complex deficiency).*

Children up to 1 year: 5ml to be taken 3 times daily.

Children 1 to 12 years, 10ml to be taken 3 times daily.

Adults: 10 to 15ml to be taken 3 times daily.

## Method of administration

For oral administration.

### **4.3 Contraindications**

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

### **4.4 Special warnings and precautions for use**

Store below 30°C .Protect from light.

### **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

### **4.9 Overdose**

Not applicable.

## **5.0 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamics properties**

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

### **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**

Vanilla essence powder,

Sucralose

Disodium Edetate

Xanthan gum

Sorbitol 70% solution

Sodium benzoate.

### **6.2 Incompatibilities**

None known.

### **6.3 Shelflife**

2 years

### **6.4 Special precautions for storage**

Store below 30°C

### **6.5 Nature and contents of container**

100ml amber glass bottle.

### **6.6 Special precautions for disposal**

No special requirements

## **7 APPLICANT/MANUFACTURER**

Afrab Chem Limited

22 Abimbola Street, Isolo Industrial Estate, Isolo-Lagos, Nigeria