

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1. NAME OF THE MEDICINAL PRODUCT

Harivite 0.6mg/ml

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains	Vit A..... 4000 I.µ	Vit. B <sub>2</sub> .....0.4mg
	Vit B.....1mg	Vit. B <sub>6</sub> .....0.5mg

Excipients: Also Contains Sugar Vit. C.....2.5mg

Vit. D<sub>3</sub>.....400 I.µ

For a full list of excipients, see section 6.1

Nicotinamide..... 5mg

### 3. PHARMACEUTICAL/FOM

Syrup

Yellow coloured liquid

### 4. CLINICAL PARTICULARS

#### 4.1 Therapeutic Indications

Harivite Multivitamin Drops is a dietary supplement, indicated for the prevention and treatment of loss of appetite and any condition that may lead to the depletion of vitamins of the body. Harivite is indicated for loss of appetite and poor eating habits. Anorexia after a brief illness. Patient experiencing loss of appetite during convalescence following surgery or after any major illness.

#### 4.2 Posology and Method of Administration

##### Posology

##### **Standard Dosage**

From 0 to 5 months, 0.3ml (Approx. five drops daily), from 6 months to 2 years 0.6ml (Approx. 10 drops daily) or as directed by the Doctor. Use a medication measuring device to carefully measure the prescribed dose. Do not use a household spoon.

##### During of Treatment

The duration of treatment should be 30 days.

##### Method of Administration

Harivite Syrup is for oral administration with or without food.

#### 4.3. Contraindications

Contraindication in patients known to be hypersensitivity to any of its components and

in patients with hypervitaminosis. Hypersensitivity: Undiagnosed anemias, hemochromatosis, Wilson's disease, pre-existing hypervitaminosis.

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

##### **Cautions;**

Adult preparations may contain iron at amounts not suitable for children: Severe iron toxicity may occur.

Use caution in severe hepatic or renal impairments RDA values are not required amounts but recommended daily allowances of certain nutrients. Some products may contain phenylalanine, which is contraindicated in phenylketonuria.

- ❖ Avoid taking similar vitamin supplements together to avoid vitamin overdose which may result in serious life threatening side effect.
- ❖ Use of salt substitute in the diet should be stopped if the multivitamin supplements contain high amount of potassium.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

##### **Pharmacokinetic Interaction**

Harivite enters the blood stream, where it distributes to the peripheral compartment, equilibrating rapidly with plasma, red blood cells, liver and kidney and more slowly with adipose tissue, muscle and skin. The latter slow redistribution is responsible for the long terminal half-life of drugs and vitamins.

The most commonly reported undesirable effects are constipation, dark stools, Nausea, vomiting, Abdominal pain.

Some people may have a feeling of lightheadedness, sleepy, blurred eyesight or a change in thinking clearly. Avoid tasks or actions that call for being alert or have clear eyesight until you see how this drug works. Stomach pain, dry mouth may be reported unexpected excitement may rarely happen.

## **5. PHARMACEUTICAL PARTICULARS**

### **5.1. List of Excipients**

Methyl Paraben

### **5.2 Incompatibilities**

Not applicable

### **5.3. Shelf life**

2 years

**5.4 Special Precautions for storage**

Store in a cool place below 30<sup>0</sup>C and away from children.

**5.5 Nature and contents of container**

15ml glass bottle in a mono carton along with dropper assembly & pack insert.

**5.6 Special precautions for disposal**

No special requirements

**6. Manufacturing Premises**

A.C. DRUGS LIMITED

Plot C5/C6 Old Airport Road

Emene, Enugu

Enugu State, Nigeria.

**7. Manufacturing premises authorization number**

Enu2023db0d0a

**8. Date of First Authorization/Renewal of the Authorization**

Date of first authorization

Date of last renewal

**9. Date of revision of text**