

## **SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE MEDICINAL PRODUCT

FERUP SOFTULES(Iron, Minerals & Vitamins) Softules 152mg/15mg/15mcg/1.5mg

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

### Each Softule contains:

Ferrous Fumarate BP 152 mg

Zinc Sulphate BP 15 mg

Vitamin B<sub>12</sub> BP 15 mcg

Folic Acid BP 1.5 mg

Excipients q.s.

Colour: Ponceau 4R, Titanium Dioxide

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Soft Capsules

Dark Red colored, oval shaped softules with homogeneously, viscous, peppermint flavored suspensions.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Ferup is a general tonic in all types of anaemia due to iron deficiency, weakness, lack of appetite, convalescence, run down conditions, during pregnancy and after delivery.

### 4.2 Posology and method of administration

One capsules before meal or as directed by the Physicians.

### 4.3 Contraindications

Hypersensitivity to ferrous fumarate, haemochromatosis, haemolytic anemia and polycythemia.

### 4.4 Precautions

No precautions are required while patient is on Ferup therapy.

### 4.5 Interaction

Antacids, tea, coffee, eggs or mils reduces the absorption of iron. The absorption penicillamine and tetracycline are impaired by iron preparations.

#### **4.6 Adverse Reactions**

Ferup is generally well tolerated by the patients. Abdominal discomfort and constipation may occur rarely.

#### **4.7 Overdose**

Ingestion of an overdose of iron orally requires emergency treatment along the following lines:

Vomiting should be induced immediately, followed (as soon as possible) by parenteral injection or desferrioxamine mesylate and then gastric lavage. In the meantime, it is helpful to give milk and/or 5% sodium bicarbonate solution by mouth.

### **5. PHARMACOLOGICAL PROPERTIES**

Ferrous fumarate is used as a source of iron for iron deficiency anemia. It contains approximately 33% elemental iron. Iron is irregularly and incompletely absorbed from gastro-intestinal tract, the major sites of absorption being the duodenum and jejunum. Absorbed iron is bound to plasma transferrin and enters the general circulations. Iron bound to transferrin is taken into erythroblasts in bone marrow and used for synthesis of hemoglobin.

The use of supplemental folic acid may be indicated in patients with increased requirements for this vitamin. Folic acid administration may reduce the risk of neural tube defects in the developing fetus. Folic acid has also been shown to reduce circulating homocysteine levels in blood. Elevated homocysteine plasma level are associated with increased risk of preeclampsia, neural tube defects, myocardial infarction and atherosclerosis.

Cyanocobalamin (Vitamin B<sub>12</sub>) is essential for cell growth and replication. It is stored in the liver. Vitamin B<sub>12</sub> takes part in the myelin synthesis of the nerves and in the process of erythrocyte maturation. Deficiency of this vitamin may cause neurological disorders and pernicious anemia. Cyanocobalamin is absorbed by binding to proteins present in gastric secretion (intrinsic factor). Zinc is an essential element of nutrition and traces are present in a wide range of foods. It is constituent of many enzyme systems and is an integral part of insulin. Zinc salts (generally zinc sulphate) are used as supplements to correct zinc deficiency; they have been tried in the treatment of a large number of conditions because of an associated reduced concentration of zinc in the body. Zinc sulphate is partially absorbed from the gastrointestinal tract; only a small proportion of dietary zinc is absorbed. Zinc is distributed widely through the body and excreted in the faeces with only traces appearing in the urine since the kidney have little or no role in regulating the content of zinc in the body.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of Excipients

Lecithin  
Butylated Hydroxy Anisole  
Butylated Hydroxy Toluene  
Methyl Paraben  
Propyl Paraben  
Oil Menthol  
Gelatin  
Sodium Citrate  
Bees wax  
Colloidal ,Silicon Dioxide  
Cottonseed Oil

### 6.2 Incompatibilities

Not applicable

### 6.3 Shelf life

2 years

### 6.4 Special precautions for storage

Store below 25<sup>0</sup>c. Protect from light.

### 6.5 Nature and contents of container

4 x 30 Softules

### 6.6 Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

## 7.0 MARKETING AUTHORISATION HOLDER

**Name:** Zydus Lifesciences Limited

**Address:** Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, Ahmedabad, Gandhinagar GJ 38248, India.

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

07143/08127/REN/2021

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

Date of first authorisation : 08/01/2004

Date of latest renewal : 21/02/2022

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

November 2023

**11. REFERENCE**