

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1. NAME OF THE MEDICINAL PRODUCT

Hemovit Capsules

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains: Ferrous Fumarate (Equivalent to Elemental Iron) 100 mg, Ascorbic Acid (Vitamin C) 75 mg, Folic Acid 0.75 mg, Cyanocobalamin (Vitamin B<sub>12</sub>) 5 mcg and Zinc Sulphate 5 mg.

*For full list of excipients, see section 6.1*

### 3. PHARMACEUTICAL FORM

Capsule

Body – Deep Red Coloured with yellow “HEMOVIT” print; Cap – Deep Red Coloured with white “Shelys” Print capsules.

### 4. CLINICAL PARTICULARS

#### 4.1 Therapeutic Indications

Hemovit Capsules are indicated in case of iron deficiency as in nutritional microcytic anaemia, iron deficiency anaemia, for prophylaxis of anaemia in pregnant and lactating women growing children, anaemia following blood loss, tropical disease, worm infestation, bacterial or protozoal infection or following surgery, as nutritional supplement during old age, adolescence or coalescence.

#### 4.2 Posology and Route of Administration

##### **Dosage**

Capsules – Children: 1 Capsule daily  
- Adult: 1-2 Capsule daily

##### **Administrative Route**

Oral Administration only

#### 4.3 Contraindications

Hemovit Capsules should not be given to patients who are receiving repeated blood transfusions or in patients with anaemia not produced by iron deficiency.

#### 4.4 Special warning and precautions for use

Hemovit Capsules should not be given together with antibiotics like tetracycline or antacid since they reduce the iron absorption.

It should be given with care to patients with hyperoxpaluria because of ascorbic acid.

Hemovit Capsules should be used with caution in patients with sideroblastic anaemia not due to iron deficiency.

History of peptic ulcer. Keep the medicine out of reach of children.

#### 4.5 Interaction with other medicinal products and other forms of interactions

If you use other drugs or over the counter products at the same time, the effects of Hemovit Capsules may change. This may increase your risk for side-effects or cause your drug not to work properly. Tell your doctor about all the drugs, vitamins, and herbal supplements you are using, so that your doctor can help you prevent or manage drug interactions. Hemovit Capsules may interact with the following drugs and products:

- Ciprofloxacin
- Demeclocycline
- Doxycycline

- Levofloxacin
- Norfloxacin
- Ofloxacin
- Tetracycline

#### **4.6 Pregnancy and lactation**

##### **Cyanocobalamin**

Hemovit Syrup can be used during pregnancy and lactation at recommended dosage

#### **4.7 Effects on ability to drive and use machines**

Not stated

#### **4.8 Undesirable Effects**

Hemovit Capsules may produce gastro-intestinal disturbances like irritation, diarrhoea, abdominal pain, nausea, vomiting and hypersensitivity reactions in some individuals.

#### **4.9 Overdose**

Large doses of Hemovit Capsules may cause convulsions and precipitate fits in epileptics, hepatic damage may also occur. Less frequent complications include; cardiac damage, generalized bleeding, renal damage and hypoglycaemia.

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic Properties**

##### **Ferrous Fumarate**

Iron is an essential constituent of the body, and is necessary for haemoglobin formation and the oxidative processes of living tissues. Iron and iron salts should be given for the treatment or prophylaxis of iron deficiency anaemias. Preparations of iron are administered by mouth, by intramuscular or intravenous injection.

Soluble ferrous salts are most effective by mouth. Ferrous fumarate is an easily absorbed source of iron for replacement therapy. It is a salt of ferrous iron with an organic acid and is less irritant to the gastro-intestinal tract than salts with inorganic acids.

##### **Folic Acid**

Folic acid is a member of the vitamin B group which is reduced in the body to tetrahydrofolate, a co-enzyme active in several metabolic processes and produces a haemopoietic response in nutritional megaloblastic anaemias. Folic acid is rapidly absorbed and widely distributed in body tissues.

##### **Ascorbic Acid (Vitamin C)**

Ascorbic acid, coupled with dehydroascorbic acid to which it is reversibly oxidised, has a variety of functions in cellular oxidation processes. Ascorbic acid is required in several important hydroxylations, including the conversion of proline to hydroxyproline (and thus collagen formation e.g. for intercellular substances and during wound healing); the formation of the neurotransmitters 5-hydroxytryptamine from tryptophan and noradrenaline from dopamine, and the biosynthesis of carnitine from lysine and methionine. Ascorbic acid appears to have an important role in metal ion metabolism, including the gastrointestinal absorption of iron and its transport between plasma and storage organs.

There is evidence that ascorbic acid is required for normal leucocyte functions and that it participates in the detoxification of numerous foreign substances by the hepatic microsomal system. Deficiency of ascorbic acid leads to scurvy, which may be manifested by weakness, fatigue, dyspnoea, aching bones, perifollicular hyperkeratosis, petechia and ecchymosis, swelling and bleeding of the gums, hypochromic anaemia and other haematopoietic disorders, together with reduced resistance to infections and impaired wound healing.

## **Cyanocobalamin (VitaminB<sub>12</sub>)**

Cyanocobalamin is a man-made form of vitamin B12 used to prevent and treat low blood levels of this vitamin. Most people get enough vitamin B12 from their diet. Vitamin B12 is important to maintain the health of your metabolism, blood cells, and nerves. Serious vitamin B12 deficiency may result in a low number of red blood cells (anemia), stomach/intestine problems, and permanent damage. Vitamin may occur in certain health conditions (such as intestinal/stomach problems, poor nutrition, cancer, HIV infection, pregnancy, old age, alcoholism). It may also occur in people who follow a strict vegetarian (vegan) diet.

## **Zinc Sulphate**

Zinc sulfate is a zinc salt used for the treatment of zinc deficiency. Zinc sulfate contains 23 percentage of elemental zinc. Zinc sulfate is absorbed over a broad pH range and may cause mild GI irritation. Zinc is an essential element of nutrition and traces are present in wide range of foods. It is a constituent of many enzyme systems and is present in all the tissues.

Normal growth and tissue repair depend upon adequate zinc. Zinc acts as an integral part of several enzymes important to protein and carbohydrates metabolism.

Features of zinc deficiency include growth retardation and defects of rapidly dividing tissues such as the skin and the intestinal mucosa. Zinc facilitates wound healing and helps maintain normal growth rates, normal skin hydration and senses of taste and smell.

Zinc improves absorption of water electrolytes. Zinc supplements prevent subsequent episodes of diarrhea. WHO and UNICEF recommend daily zinc supplements for children with acute diarrhea to curtail the severity of the episode and prevent further occurrences in the ensuing 2-3 months. Zinc deficiency in human alters several aspects of immune function. Immune defects associated with zinc deficiency include impaired function of lymphocytes, natural killer cells and neutrophils. Zinc deficiency has also been hypothesized to exacerbate malaria and other diseases (infection with human immunodeficiency virus and tuberculosis) that rely on macrophage killing of infected cells. Adequate intakes of zinc shorten the duration of respiratory tract infections including common cold.

## **5.2 Pharmacokinetic Properties**

### **Ferrous Fumarate**

#### **Absorption**

Once in the stomach, the acid conditions of the gastric contents cause the dissociation of ferrous fumarate and ferrous ions are liberated. These ions are absorbed through the proximal portion of the duodenum.

The ferrous iron absorbed by the mucosal cells of the duodenum is oxidised to the ferric form, and this is bound to protein to form Ferritin.

#### **Distribution**

Ferritin in the mucosal cells releases iron into the blood, where it is bound to transferrin and is passed onto the iron stores in the liver, spleen, and bone marrow.

These stores constitute a reserve of iron for synthesis of haemoglobin, myoglobin, and iron containing enzymes.

#### **Elimination**

Iron is lost from the body through loss of cells i.e, urine, faeces, hair, skin, sputum, nails, sloughing of mucosal cells, and through blood loss.

Ferrous fumarate has the same pattern of absorption and excretion as dietary iron.

## **Folic Acid**

### **Absorption**

Folic acid is rapidly absorbed from the gastrointestinal tract, mainly from the proximal part of the small intestine. Dietary folates are stated to have about half the bioavailability of crystalline folic acid. The naturally occurring folate polyglutamates are largely deconjugated and reduced by dihydrofolate reductase in the intestine to form 5-methyltetrahydrofolate (5MTHF). Folic acid given therapeutically enters the portal circulation largely unchanged, since it is a poor substrate for reduction by dihydrofolate reductases.

### **Distribution**

Via portal circulation. 5MTHF from naturally occurring folate is extensively plasma bound. The principal storage site of folate is in the liver; it is also actively concentrated in the CSF. Folate is distributed into breast milk.

### **Biotransformation**

Therapeutically given folic acid is converted into the metabolically active form 5MTHF in the plasma and liver. There is an enterohepatic circulation for folate.

### **Elimination**

Folate metabolites are eliminated in the urine and folate in excess of body requirements is excreted unchanged in the urine. Folic acid is removed by haemodialysis.

## **Ascorbic Acid (Vitamin C)**

### **Absorption**

Ascorbic acid is well absorbed from the gastrointestinal tract.

### **Distribution**

Ascorbic acid is widely distributed to all tissues. Body stores of ascorbic acid normally are about 1.5g. The concentration is higher in leucocytes and platelets than in erythrocytes and plasma.

### **Elimination**

Ascorbic acid additional to the body's needs, generally amounts above 200mg daily, is rapidly eliminated; unmetabolised ascorbic acid and its inactive metabolic products are chiefly excreted in the urine. The amount of ascorbic acid excreted unchanged in the urine is dose-dependent and may be accompanied by mild diuresis.

## **Cyanocobalamin (VitaminB<sub>12</sub>)**

### **Absorption**

The absorption of cobalamins from the gut is dependent upon the glycoprotein intrinsic factor.

### **Distribution**

Cobalamins are transported rapidly into the blood bound to protein, known as transcobalamins.

### **Elimination**

Cobalamins are stored in the liver and excreted in the bile. They are known to cross the placenta.

## **Zinc Sulphate**

Zinc is absorbed from the gastrointestinal tract and distributed throughout the body. The highest concentrations occur in hair, eyes, male reproductive organs and bone. Lower levels are present in liver, kidney and muscle. In blood 80% is found in erythrocytes. Plasma zinc levels range from 70 to 110µg/dL and about 50% of this is loosely bound to albumin. About 7% is amino-acid bound and the rest is tightly bound to alpha 2-macroglobulins and other proteins.

## **5.3 Preclinical safety data**

There are no preclinical data of relevance to the prescriber in addition to that included in other sections of the summary of product characteristics.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Maize Starch, Purified Talc Powder, Magnesium Stearate, Light Liquid Paraffin and Hard Gelatin Capsules.

### **6.2 Incompatibilities**

Not Applicable

### **6.3 Shelf life**

36 months

### **6.4 Storage Conditions**

Store in a cool dry place below 30°C away from direct light, Keep out of reach of children.

### **6.5 Nature of Primary Packaging**

Hemovit Capsules is blistered with aluminium foil and PVC then packed in a dispenser of 30's

### **6.6 special precautions for disposal and other handling**

Not special instructions for use/ handling

## **7.0 MARKETING AUTHORIZATION HOLDER**

**Name:** Shelys Pharmaceuticals Limited

**Address:** Plot No. 696, New Bagamoyo Road, Mwenge, Dar es salaam, Tanzania

**Telephone:** +255 22 2771715/6/7

**Telefax:** +255 22 2772417

**E-mail:** [info@tz.betashelys.com](mailto:info@tz.betashelys.com)

## **MANUFACTURING SITE ADDRESSES**

**Name:** Shelys Pharmaceuticals Limited

**Address:** Plot No. 696, New Bagamoyo Road, Mwenge, Dar es salaam, Tanzania

**Telephone:** +255 22 2771715/6/7

**Telefax:** +255 22 2772417

**E-mail:** [info@tz.betashelys.com](mailto:info@tz.betashelys.com)

And;

**Name:** Beta Healthcare International Limited

**Address:** Plot No. LR 209/6554, Mogadishu Road, Industrial Area, Nairobi,

**Postal Address:** P.O. Box 42569-00100, Nairobi, Kenya

**Telephone:** +254202652042/89

**Telefax:** +25420556198

**E-mail:** [info@ke.betashelys.com](mailto:info@ke.betashelys.com)

## **8. MARKETING AUTHORIZATION NUMBER(S)**

TAN 22 HM 0089

## **9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION**

11/04/2022

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