

For consumer information only

# FEMSMART-XT<sup>®</sup>

(Ferrous Ascorbate, Zinc & L-methylfolate Tablets)

## **Red Blood Cells (RBCs) & Hemoglobin:**

Widely present blood cells in body. It contains red pigment hemoglobin (Hb) which binds and transports O<sub>2</sub> & CO<sub>2</sub>. Average Life span of Red Blood Cells is 120 days .RBCs contains iron containing Hemoglobin. Hemoglobin is made up of four subunits: 2 alpha subunits and 2 beta subunits. Each unit surrounds a central heme group that contains iron and binds 1 oxygen molecule. Molecules with more oxygen bound to the heme groups are bright red so; oxygenated arterial blood where the Hb is carrying 4 oxygen molecules is bright red, while venous blood that is deoxygenated blood is dark in color.

## **Formation of RBCs or Erythropoiesis:**

- Erythropoiesis ('Erythro' meaning "red" and 'poiesis' meaning "to make") is the process which produces red blood cells (erythrocytes).
- Erythropoietin (EPO) is the key hormone responsible for effective erythropoiesis, and iron is the essential mineral required for Hb synthesis. EPO allows survival and proliferation of erythroid precursor cells by generating intracellular signals.
- Erythroblasts acquire iron from the serum through iron-bound transferrin mediated uptake through the transferrin receptor.
- Because the body only absorbs 1-2 mg of new iron per day, the source for 90%-95% of their on used by developing red cell precursors is from the recycling of old and senescent red cells.

Iron is an essential element of various metabolic processes in humans including DNA synthesis, electron transport, and oxygen transport. Unlike other minerals, iron levels in the human body are controlled only by absorption. The mechanism of iron excretion is an unregulated process arrived at through loss in sweat, menstruation, shedding of hair and skin cells, and through rapid turnover and excretion of enterocytes. In the human body, iron exists mainly in erythrocytes as the heme compound hemoglobin (approximately 2 g of iron in men and 1.5 g in women), to a lesser extent in storage compounds (ferritin and hemosiderin) and in muscle cells as myoglobin. Iron also is found bound to proteins (hemoprotein) and in non-heme enzymes involved in oxidation reduction reactions and the transfer of electrons (cytochromes and catalase).

**Anemia** is a disorder characterized by low oxygen transport capacity of the blood, because of either low red blood cells (RBCs) count or abnormality of red blood cells or Hemoglobin (Hb).

**The prevalence of anemia ...higher in India ...compared to all other developing countries. Anemia is 2<sup>nd</sup> leading cause of maternal deaths in the country. 50 % of women of reproductive age & 26 % of men in the age group of 15-59 years are anaemic. Anaemia is a common complication of chronic kidney disease (CKD). Early erythropoietin- deficiency anaemia occurs in both type 1 and type 2 diabetes. Higher frequency in Rheumatoid arthritis patients. So let's fight against anemia smartly**

### **What is Femsmart-XT?**

#### **Composition:**

Each film coated tablet contains:

Ferrous Ascorbate Eq. to elemental Iron .....	100mg
Zinc Sulphate Monohydrate IP.....	61.8mg
Eq. to elemental zinc.....	22.5mg
L-methyl folate Calcium Eq. to L-methyl folate.....	1 mg
Excipients.....	q.s.

**Colour:** Red oxide of iron & Titanium Dioxide IP

#### **Clinical Pharmacology:**

##### **Ferrous Ascorbate:**

Ferrous ascorbate is a synthetic molecule of iron and ascorbic acid. The ferrous form is absorbed thrice as much as the ferric form of iron. There is no dissociation of ferrous ascorbate on entering the gastrointestinal (GI) tract due to the stable chelate of iron with ascorbate. Ascorbic acid reduces ferric iron to ferrous iron, which remains soluble even at neutral pH, and enhances the absorption of iron. It also inhibits the conversion of ferrous to ferric iron; this maintains the iron in highly soluble ferrous form, leads to increased absorption of iron and reduces the amount of free radicals generated, thereby minimizing adverse GI effects. Ascorbic acid has been shown to inhibit the effect of phytates, phosphates and oxalates on iron absorption by the formation of soluble iron ascorbate complexes and by inhibiting the formation of insoluble iron complexes. Iron combines with porphyrin and globin chains to form hemoglobin, which is critical for oxygen delivery from the lungs to the tissues. Iron deficiency causes a microcytic anemia due to the formation of small erythrocytes with insufficient hemoglobin.

**L-Methylfolate:**

The term folate is typically used as a generic name for the group of chemically related compounds based on the folic acid structure. Folate, or vitamin B9, is thought of as one of the 13 essential vitamins. It cannot be synthesized de novo by the body, and must be obtained either from diet or supplementation. Dietary folate is a naturally occurring nutrient found in foods such as leafy green vegetables, legumes, egg yolk, liver, and citrus fruit. Folic acid is a synthetic dietary supplement that is present in artificially enriched foods and pharmaceutical vitamins. Neither folate nor folic acid is metabolically active. Both must be reduced to participate in cellular metabolism. L-5-Methyltetrahydrofolate (L-methylfolate) is the predominant micronutrient form of folate that circulates in plasma and that is involved in biologic processes. To become metabolically active, folic acid must first be converted to dihydrofolate (DHF) and then tetrahydrofolate (THF) through enzymatic reduction, a process catalyzed by the enzyme DHF reductase (DHFR). Thereafter, THF can be converted to the biologically active L-methylfolate by the enzyme methylene tetrahydro folate reductase (MTHFR). This key conversion is necessary to provide L-methylfolate for the one-carbon transfer reactions (methyl donations) needed for purine/pyrimidine synthesis during DNA and RNA assembly, for DNA methylation, and to regulate homocysteine metabolism.

**Zinc:**

It is an essential trace mineral, is required for the metabolic activity of 300 of the body's enzymes, and is considered essential for cell division and the synthesis of DNA and protein. Zinc ions ( $Zn^{2+}$ ) are closely involved in the normal development, differentiation, and function of immune cells, thus considered critical for generating both innate and acquired (humoral) antiviral responses. Zn is involved in various cellular processes and possesses a variety of direct and indirect antiviral properties. It was demonstrated that Zn deficiency is associated with reduced antibody production, affected function of the innate immune system (e.g., low natural killer cell activity), decreased cytokine production by monocytes, and the chemotaxis and oxidative burst of neutrophil granulocytes. It also results in thymic atrophy, altered thymic hormones production, lymphopenia, and defective cellular- and antibody-mediated responses that lead to increased rates and duration of infection. In particular, Zn deficiency reduces the number of peripheral and thymic T cells, their proliferation in response to phytohemagglutinin, and the functions of T helpers and cytotoxic T cells. In addition, Zn deficiency acts indirectly by reducing the levels of active serum thymulin, a zinc-dependent nonapeptide hormone that regulates the differentiation of immature T cells in the thymus and the function of mature peripheral T cells. On the other hand, Zn can affect several aspects of monocyte signal transduction and secretion of pro-inflammatory cytokines, and interfere with the binding of leukocyte function-associated antigen-1 to ICAM-1, thus suppressing inflammatory reaction. Zinc is also critical to tissue growth, wound healing, taste acuity, connective tissue growth and

maintenance, immune system function, prostaglandin production, bone mineralization, proper thyroid function, blood clotting, cognitive functions, fetal growth and sperm production.

Zinc plays a very important and critical role in various functions of the human body including protein synthesis and nucleic acid metabolism

**Indication:**

- ❖ Iron deficiency anemia.
- ❖ Pregnancy & lactation.
- ❖ Chronic and acute blood loss.
- ❖ Rheumatoid arthritis related conditions.
- ❖ Chronic kidney diseases.

**Dosage and Administration:**

One tablet per day, or as directed by the physician.

**Contraindications:**

Patients hypersensitive to ferrous ascorbate, L- Methyl Folate or to any other component of this formulation; Patients with porphyria cutanea tarda, haemochromatosis and haemosiderosis, and haemolytic anaemia.

**Warnings and Precautions:**

General: Do not exceed the recommended dose. The type of anaemia and the underlying cause or causes should be determined before starting therapy with this medication. Since the anaemia may be a result of a systemic disturbance, such as recurrent blood loss, the underlying cause or causes should be corrected, if possible.

**Drug interaction:**

The administration of the following results in decreased iron effectiveness: Aluminium hydroxide, aluminium phosphate, calcium , aluminium carbonate (basic), chloramphenicol, dihydroxyaluminium aminoacetate, dihydroxyaluminium sodium carbonate, magaldrate, magnesium carbonate, magnesium hydroxide, magnesium oxide, magnesium trisilicate, methacycline, minocycline, oxytetracycline, rolitetracycline, sodium bicarbonate.

Also following molecules decreased iron effectiveness: Cefdinir, cinoxacin, ciprofloxacin, enoxacin, gatifloxacin, gemifloxacin, grepafloxacin, levofloxacin, lomefloxacin, moxifloxacin, norfloxacin, ofloxacin, penicillamine, sparfloxacin, temafloxacin, trovafloxacin mesylate, levothyroxine.

**Vanilin Coated tablet.**

**Storage:** Store at temperature below 25<sup>0</sup>. Protect from light and moisture.

Keep all medicines out of reach of children.

**Warning:** To be sold by retail on the Prescription of a Registered Medical Practitioner only.

**For Therapeutic Use.**

**Route of administration:** Oral

**Presentation:** FEMSMART-XT is available as 10 X 10 Tablets.

**Marketed By:**



**EPIONE PHARMACEUTICALS PVT.LTD.**

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