For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

(Ferrous Ascorbate, Folic Acid Tablets)
HEMFER-XT

1. Name of the medicinal product
Hemfer-XT
2. Qualitative and quantitative composition
Each film coated tablet contains:
Ferrous Ascorbate equivalent to Elemental Iron .....100mg Folic Acid I.P..... 1.5mg
Excipients .....q.s.
3. Pharmaceutical form
Film-coated tablets.
4. Clinical particulars
4.1 Therapeutic indications
For the treatment of iron deficiency anaemia.
4.2 Posology and method of administration
One tablet to be taken once daily or as directed by a physician.
4.3 Contraindications
Hypersensitivity to any constituent of the product.
Iron overload conditions such as Hemochromatosis and hemosiderosis.
Long-term folate therapy is contraindicated in any patient with untreated cobalamin deficiency or Addisonian pernicious anaemia because it may precipitate the onset of subacute combined degeneration of the spinal cord.
Folic acid should not be used in malignant disease unless megaloblastic anaemia owing to folate deficiency is an important complication.
4.4 Special warnings and precautions for use
Ferrous Ascorbate
Iron compounds should not be given to patients in following conditions;

- Receiving repeated blood transfusions or to patients with anaemias not produced by iron deficiency.
- Already parenteral iron therapy continues.
- Iron-storage or iron-absorption diseases such as haemochromatosis, haemoglobinopathies
- Existing gastrointestinal diseases such as inflammatory bowel disease, intestinal strictures and diverticulae.
- Non-deficient subjects because increased risk of microbial infection after supplementation, in children without iron deficiency may retard their growth, iron may be associated with ischaemic heart disease, by modifying low-density lipoprotein in ways which increase its atherogenic potential and by sensitising the myocardium to ischaemic injury.

Folic Acid
Patients with rare hereditary problems of galactose intolerance, the lapp lactase deficiency or glucose - galactose malabsorption should not take this medicine and caution should be exercised to patients who may have folate dependent tumours.
Folic acid should never be given alone or with inadequate amounts of vitamin B12 for the treatment of undiagnosed megaloblastic anaemia, since folic acid may produce a haematopoietic response

in patients with a megaloblastic anaemia due to vitamin B12 deficiency without preventing aggravation of neurological symptoms. This masking of the true deficiency state can lead to serious neurological damage, such as subacute combined degeneration of the s spinal cord.

4.5 Interaction with other medicinal products and other forms of interaction

Ferrous Ascorbate

Compounds containing calcium and magnesium, including antacids and mineral supplements, and bicarbonates, carbonates, oxalates, or phosphates, tetracyclines, trientine, acetohydroxamic acid, chloramphenicol, levothyroxine, cefdinir, bisphosphonates, entacapone, fluoroquinolones, levodopa, methyldopa, mycophenolate mofetil, and penicillamine and Zinc salts may impair the absorption of iron. Some agents, such as ascorbic acid and citric acid, may actually increase the absorption of iron. Iron should not be given with dimercaprol as toxic complexes may form.

Folic Acid

Antiepileptics (phenytoin, phenobarbital and primidone), the serum antiepileptic levels may fall, Antibacterials (chloramphenicol and co-trimoxazole) may interfere with folate metabolism. Sulfasalazine - can reduce the absorption of folic acid. Folic acid may interfere with the toxic and therapeutic effects of methotrexate.

4.6 Pregnancy and lactation

Pregnancy

Either animal-reproduction studies have not demonstrated a fetal risk but there are no controlled studies in pregnant women or animal-reproduction studies have shown adverse effects (other than a decrease in fertility). There is no evidence of a risk in later trimesters.

Lactation

Available evidence and/or expert consensus are inconclusive or are inadequate for determining infant risk when used during breastfeeding. Weigh the potential benefits of drug treatment against potential risks before prescribing this drug during breastfeeding.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Ferrous Ascorbate

Gastrointestinal irritation and abdominal pain with nausea and vomiting, diarrhoea or constipation and black colored stool. Adverse effects can be reduced by giving it with or after food (rather than on an empty stomach) or by beginning therapy with a small dose and increasing gradually.

Folic Acid

Gastrointestinal disorders Rare (1/10,000 till <1/1,000)	Anorexia, nausea, abdominal distension and flatulence
Immune system disorders Rare (1/10,000 till <1/1,000)	Allergic reactions, comprising erythema, rash, pruritus, urticaria, dyspnoea, and anaphylactic reactions (including shock)

4.9 Overdose

Ferrous Ascorbate

Because the body lacks a mechanism for the excretion of excess iron, abnormally high absorption or repeated blood transfusion will result in iron overload, leading eventually to haemochromatosis. The consequences of haemochromatosis include pigment deposition in skin and other organs, mild liver dysfunction, endocrine dysfunction (failure of the adolescent growth spurt, hypogonadism, ischaemic heart disease sometimes diabetes and hypothyroidism), and heart disease (pericarditis, heart failure, and arrhythmias). If unchecked, the iron build-up can

lead to death, mainly through heart failure or arrhythmia. Where iron overload is due to increased absorption, phlebotomy is the treatment of choice; however, if phlebotomy is not tolerated or in patients who are transfusion-dependent (as in β-thalassaemia) treatment with iron chelators such as desferrioxamine is used to retard accumulation. Activated charcoal is ineffective, but gastric lavage should be considered in those who have ingested the equivalent of more than 60 mg/kg of elemental iron within 1 hour of presentation. Serum-iron concentrations may be an aid to estimating the severity of poisoning.

Folic Acid

No special procedures or antidote are likely to be needed.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Ferrous Ascorbate

Iron is an essential component in the formation of hemoglobin. Adequate amount of iron is required for effective erythropoiesis. Iron also serves as a cofactor of several essential enzymes, including cytochromes that are involved in electron transport.

Folic acid

Folic acid is required for nucleoprotein synthesis and the maintenance of normal erythropoiesis. Folic acid is converted in the liver and plasma to its metabolically active form, tetrahydrofolic acid, by dihydrofolate reductase.

5.2 Pharmacokinetic properties

Ferrous Ascorbate

Iron is irregularly and incompletely absorbed mainly from duodenum and jejunum. Its absorption is enhanced by haem complex form, acidity, in fasting and iron deficiency state and its decreases if the body stores are overloaded.

Most absorbed iron is bound to transferrin and transported to the bone marrow where it is incorporated into haemoglobin; the remainder is contained within the storage forms, ferritin or haemosiderin, or as myoglobin, with smaller amounts occurring in haem containing enzymes or in plasma bound to transferrin. Only very small amounts of iron are excreted as the majority released after the destruction of the haemoglobin molecule is re-used.

Folic Acid

Absorption – folic acid is rapidly absorbed from the gastrointestinal tract, mainly from the proximal part of the small intestine. 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.

Metabolism – 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.

6. Pharmaceutical particulars

6.1 Shelf life

24 Months. The expiry date is indicated on the label and packaging.

6.2 Special precautions for storage

Store in a cool dry place, Protected from light.

6.3 Nature and contents of container

Alu/Alu Blister Foil.

7. Marketed By

ALKEM
Alkem Laboratories Ltd.
ALKEM HOUSE,
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