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SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Medicinal Product

Product Name:-I-UP SUSPENSION (Ferrous Ascorbate & Folic Acid Suspension)

Strength :

Ferrous Ascorbate equivalent to Elemental Iron……. 30 mg

Folic Acid BP ….. 550 mcg

2. QUALITATIVE AND QUANTITATIVES COMPOSITION:

Each 5 ml contains:

Ferrous Ascorbate equivalent to Elemental Iron……. 30 mg

Folic Acid BP ….. 550 mcg

Colour : Caramel USP/NF

For the full list of excipients, see section 6.1.

3. Pharmaceutical form:

Syrup for Oral use

Visual description of finished product: Dark brownish coloured viscous liquid having sweet taste & pleasant flavor.

4. Clinical particulars:

4.1 Therapeutic indications:

Indicated in the treatment of iron deficiency anemia, menorrhagia and folate deficiency anemia.

Ferrous ascorbate reduces the risk of pre-eclampsia (pregnancy-induced hypertension) which bgenerally occurs in severe or very severe anemia. Folic acid can reduce the risk of fetal neural tube defects.

4.2 Posology and method of administration

1-2 teaspoonful daily (5-10 mL) or as directed by the physician.

4.3 Contraindications

Hypersensitivity to iron, should be avoided in patients who have bacterial infections.

Contraindicated in patients who have hemosiderosis, hemochromatosis, and hemolytic anemia.

4.4 Special warnings and precautions for use

Warning:

Oral iron may aggravate existing peptic ulcer, regional enteritis and ulcerative colitis.

4.5 Drug Interactions

Absorption of iron is inhibited by magnesium trisilicate and antacids containing carbonates.

Since oral iron products interfere with absorption of oral tetracycline antibiotics, these products should not be taken within two hours of each other. Iron absorption may also be inhibited by the ingestion of milk or eggs.

4.6 Pregnancy and lactation

For the prevention and treatment of iron deficiency and to supply a maintenance dosage of folic acid.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Side Effects

Nausea, regurgitation, constipation, pyrosis (burning sensation in the chest), upset stomach may occur with the use of hematinics.

Iron may cause your stools to turn black, an effect that is not harmful.

4.9 Overdosage

Overdose occurs only rarely in adults, but can occur in children. Toxicity due to an excessive intake is caused by iron overdosage. Initial symptoms result from the contact irritation of iron on gastrointestinal mucosa: nausea, vomiting, diarrhoea, epigastric pain, hematemeses and rectorrhages. The situation may progress and late complications are hypotension, coma, hepatocellular necrosis and renal impairment. To decrease absorption, gastric lavaging with sodium bicarbonate 1% and monitoring of the patient are recommended. In adults a solution of manitol or sorbitol may be used to stimulate the intestinal emptying. Deferoxamine (mesylate) is a chelating agent that binds ferric ions to the groups 3-hydroxamic of the molecule, being effective when administered early in the treatment of acute intoxication.

Intubation and haemodynamic therapy may be required in more severe situations.

5. Pharmacological Properties

5.1 Pharmacodynamics properties

Pharmacotherapeutic group:Antianemic, ATC code:

ferrous ascorbate: B03AA10; Folic Acid:B03BB01

Ferrous Ascorbate when administered is converted to ferric form and immediately is reduced to the ferrous form into the stomach. This reduced ferrous form is then transferred to the duodenum where it is highly absorbed. Ferrous Ascorbate has the advantage of providing both ferrous ion and ascorbate in the same compound. There is no dissociation on entering GI Tract due to the stable chelate of iron

with ascorbate. Folic Acid itself is biochemically inactive, is converted to tetrahydro folic acid and methyl tetrahydrofolate by dihydrofolate reductase in liver. These folic acid congeners are transported across cells by receptormediated endocytosis where they are needed to maintain numerous body functions.

5.2 Pharmacokinetics

Ferrous ascorbate

Absorption: Increased in iron deficiency anaemia

Distribution: Transported in a transferring bound form to bone marrow

Elimination: Excretion is minimal

Folic Acid

Absorption: Well absorbed orally

Distribution: Widely distributed in the body and highest concentration is seen in liver. It appears in the CSF and breast milk

Metabolism: Metabolized in to N-methyl tetrahydrofolic acid in liver

Excretion: Extra drug is excreted unchanged in urine. A small portion of folate is lost by a combination of urinary and fecal excretion and oxidative cleavage of molecule.

5.3 Preclinical safety data

There are no pre-clinical data of relevance.

6. Pharmaceutical particulars

6.1 List of excipients

Sucrose
Sodium Benzoate
Sodium Methyl Hydroxy benzoate
Propyl Paraben Sodium
Xanthan Gum (E415 Type-FFA)
Sorbitol Solution 70 %
(Non-Crystallizing)
Sodium Hydroxide
Flavour American Ice Cream Soda (IFF)
Flavour Vanilla (Vital)
Colour Caramel
Sucralose
Flavour Rose S4025 (IFF)
P-Amino Benzoic Acid
Purified Water (Q.S.)

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

24 Months (2 Years)

6.4 Special precautions for storage

Store in a dry place below 30°C. Protect from light.

Keep out of reach of Children.

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

I-UP SUSPENSION (Ferrous Ascorbate & Folic Acid Suspension) are packed in 200 ml amber coloured PET bottle with 10 ml measuring cups & printed label in a printed carton along with pack insert.

6.6 Special precautions for disposal and other handling

Not Applicable

7. Marketing authorization holder

Cachet Pharmaceuticals Pvt. Ltd

Address: 415, Shah Nahar, Worli, Mumbai 400 018. India.

Phone No. Office +91-22-40829991

Email: - regulatory@cachetpharma.com

8. Marketing authorization number(s)

06988/09297/NMR/2021

9. Date of first authorization/renewal of the authorization

Date of first authorization: 29.12.2021

10. Date of revision of the text

05.07.2023