SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of medicinal product

Fecontin-Z
(Controlled Release Tablets of Ferrous Glycine Sulphate and Zinc Sulphate with Folic Acid)

2. Qualitative and Quantitative composition

Core:

Name of ingredients	Unit formula (mg/tablet)	Reference to standard	Reason for inclusion
Ferrous Sulphate Dried	316.00*	BP	Active
Glycine	134.00	BP	Active
Zinc Sulphate Monohydrate	61.80	USP	Active
Natrosol 250 HX (Hydroxyethylcellulose)	15.00	BP	Retardant
Kolliwax CSA 50 (Cetostearyl Alcohol)	50.00	BP	Retardant
Talc Purified	8.00	BP	Lubricant
Magnesium Stearate	4.00	BP	Lubricant
Purified Water	0.06ml**	BP	Granulating fluid

* Assay at 86%
** Not present in final weight

Coating solution I:

Name of ingredients	Unit formula (mg/tablet)	Reference to standard	Reason for inclusion
Diethyl Phthalate	0.92	USPNF	Plasticizer
Opadry white OY-58900	10.00	In-house	Branded coating material
Hydroxypropyl methylcellulose 15 cps	4.17	USP	Film forming agent
Ethyl cellulose 10cps	0.83	USPNF	Film forming agent
Methanol	0.079 ml**	USPNF	Solvent
Methylene Chloride	158.33 ml**	BP	Solvent

Coating solution II:

Name of ingredients	Unit formula (mg/tablet)	Reference to standard	Reason for inclusion
Folic Acid	0.75*	BP	Active
Hydroxypropyl methylcellulose 15 cps	8.17	USP	Film Forming agent
Polyethylene Glycol 300	6.0	USPNF	Plasticizer
Isopropyl Alcohol	58.33**	BP	Solvent
Methylene Chloride	250.00**	BP	Solvent

Coating solution III

Name of ingredients	Unit formula (mg/tablet)	Reference to standard	Reason for inclusion
Diethyl Phthalate	0.83	USPNF	Plasticizer
Hydroxypropyl methylcellulose 15 cps	1.66	USP	Film Forming agent
Opadry OY-58900 white	6.67	In-house	Branded coating material
Ethyl cellulose 10cps	1.66	USPNF	Film forming agent
Methanol	0.05**	USPNF	Solvent
Methylene Chloride	100.0**	BP	Solvent

Coating solution IV

Name of ingredients	Unit formula (mg/tablet)	Reference to standard	Reason for inclusion
Hydroxypropyl methylcellulose 15 cps	3.33	USP	Film forming agent
Opadry 02H55103 Red	10.00	In-house	Branded coating material
Polyethylene Glycol 400	0.92	USPNF	Plasticizer
Methanol	0.075**	USPNF	Solvent
Methylene Chloride	150.0**	BP	Solvent

* Include 50% overages

** Not present in final weight

3. Pharmaceutical form

Controlled release tablets

Description: Fecontin-Z is red, round, biconvex, film-coated tablets.

4. Clinical particulars

4.1 Therapeutic indications

For the prophylaxis of iron, zinc and folic acid deficiency during pregnancy (2^{nd} and 3^{rd} trimester) and lactation.

4.2 Posology and method of administration

One tablet to be taken daily during pregnancy (2nd trimester onwards) and lactation.

Tablets should be swallowed whole and not chewed. Not to be taken with hot liquids.

4.3 Contraindications

Do not use in patients with known hypersensitivity to any ingredient, hemochromatosis, hemosiderosis, hemolytic anemia, in B_{12} deficiency anemia without concomitant B_{12} supplementation.

4.4 Warnings and Precautions

Care should be taken in patients who may develop iron overload, such as those with hemochromatosis, hemolytic anemia or red cell aplasia.

Failure to respond to treatment may indicate other causes of anemia and should be further investigated.

Folic acid in doses > 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurologic manifestations remain progressive. Except during pregnancy and lactation, folic acid should not be given in therapeutic doses > 0.4 mg daily until pernicious anemia has been ruled out.
In patients with renal failure, a risk of zinc accumulation could exist.

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

Antacids reduce GI absorption of iron. Iron and Zinc chelate with Tetracyclines and the absorption of all three agents may be impaired. Ascorbic acid and chloramphenicol increase the serum iron levels. Iron salts chelate with levodopa, levothyroxine, methyldopa and penicillamine, reducing their efficacy.

Amino salicylic acid, oral contraceptive pills, dihydrofolate reductase inhibitors (methotrexate, trimethoprim) and sulfasalazine reduces serum folic acid levels and therefore interfere with the functions of folic acid. Folate administration may reduce serum levels of anticonvulsant drugs.

Drug-Food Interactions:

Eggs, milk and phytates inhibit iron absorption. Bran products and some foods (e.g., protein, phytates, and some minerals) may decrease zinc absorption.

4.6 Pregnancy and lactation

Use of any drug during the first trimester should be avoided if possible. Thus, administration of iron during the first trimester requires definite evidence of iron deficiency. Treatment of iron deficiency during the remainder of pregnancy is justified.

Iron salts, zinc and folic acid are excreted into breast milk which may be of benefit when there is iron, zinc or folic acid deficiency in the neonates.

4.7 Effects on ability to drive and use machines.

No known effects

4.8 Undesirable effects

Dark stools are usual during iron therapy. Nausea and other symptoms of gastro-intestinal irritation, such as anorexia, vomiting, abdominal discomfort, constipation and diarrhoea are sometimes encountered. Fecontin-Z Continus tablets are designed to reduce the possibility of gastro-intestinal irritation. There have been rare reports of allergic reactions.

4.9 Overdose & Its Treatment

Iron overdosage is dangerous, particularly in children, and requires immediate attention. Treatment is necessary if more than 30 mg of elemental iron per kg body weight has been ingested. Symptoms may include abdominal pain, vomiting, diarrhoea and haematemesis, and in more severe cases coma, convulsion, shock, metabolic acidosis etc. may be precipitated. Gastric lavage should be carried out in early stages or if this is not possible, vomiting should be induced. Oral desferrioxamine (2 gm for a child and 5 gm for an adult) and demulscents should be given. If serum iron levels, at 4 hrs or more post-ingestion, are over 5mg/l in a child or 8 mg/l in an adult or if the patient is in shock or coma, intramuscular or intravenous desferrioxamine should be used.

Zinc sulphate in gross overdose is corrosive and symptoms are those of G.I. irritation, leading in severe cases to haemorrhage, corrosion of the mucosa and possibly stricture formation. Gastric lavage or emesis should be avoided. Demulscents such as milk, should be given. Chelating agents such as dimercaprol, penicillamine or edetic acid may be used, if required.

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Symptomatic and supportive measures should be given as required. The Continus release tablets may delay excessive absorption of iron and zinc and allow more time for initiation of appropriate counter measures.

5.0 Pharmacological properties

5.1 Pharmacodynamic properties

Iron, an essential mineral, is a component of hemoglobin, myoglobin and a number of enzymes (cytochromes, catalase, peroxidase). Iron is primarily stored as hemosiderin, or aggregated ferritin, found in the reticuloendothelial cells of the liver, spleen, and bone marrow. Iron deficiency can affect muscle metabolism, heat production and catecholamine metabolism, and has been associated with behavioral or learning problems in children.

Exogenous folate is required for nucleoprotein synthesis and maintenance of normal erythropoiesis. It stimulates production of red blood cells, white blood cells and platelets. Folic acid is the precursor of tetrahydro folic acid, which is involved as a cofactor for trans formylation reactions in the biosynthesis of purines and thymidylates of nucleic acids. Impairment of thymidylate synthesis in patients with folic acid deficiency is thought to account for the defective deoxyribonucleic acid (DNA) synthesis that leads to megaloblast formation and megaloblastic and macrocytic anemias.

5.2 Pharmacokinetic properties

Iron is mainly absorbed from the duodenum and upper jejunum by an active transport mechanism. The ferrous salt form is absorbed three times more readily than ferric form. The amount of iron absorbed increases progressively with larger doses; however, the percentage absorbed decreases. The daily loss of iron from urine, sweat and sloughing of intestinal mucosal cells amounts to 0.5 to 1 mg in healthy men. In menstruating women, 1 to 2 mg is the normal daily loss.

Oral synthetic folic acid is a monoglutamate and is completely absorbed following administration, even in the presence of malabsorption syndromes. Folic acid appears in the plasma 15 to 30 minutes after an oral dose. It is metabolized in the liver to 7,8- dihydrofolic acid and eventually to 5,6,7,8-tetrahydrofolic acid. Tetrahydro folic acid derivatives are distributed to all body tissues but are stored primarily in the liver.

5.3 Preclinical Safety Data

Not Applicable

6.0 Pharmaceutical particulars

6.1 List of Excipients

S. No.	Name of the Excipients
1.	Natrosol 250 HX (Hydroxyethylcellulose)
2.	Kolliwax CSA 50 (Cetostearyl Alcohol)
3.	Talc Purified
4.	Magnesium Stearate
5.	Diethyl Phthalate
6.	Opadry OY-58900 white
7.	Hydroxypropylmethylcellulose15 cps
8.	Ethyl cellulose 10cps
9.	Methanol
10	Methylene Chloride
11.	Polyethylene Glycol 300
12.	Isopropyl Alcohol
13.	Opadry 02H55103 red
14.	Polyethylene Glycol 400

6.2 Incompatibilities
Not Applicable

6.3 Shelf life
24 months from the date of manufacture

6.4 Special precautions for storage
Store at or below 30ºC, in a dry place, protected from light.

6.5 Nature and content of container
Fecontin-Z are packed in aluminium blister strips made up of printed aluminium foil (length 112 mm × thickness 0.025 mm) and PVC rigid film coated with PVDC (length 116 mm × thickness 0.25 mm)

Pack Size
Box of 100 tablets (10×10's blister strips)

6.6 Instructions for use/handling
No special requirements.

7.0 Marketing authorization holder

Manufactured by:
Modi-Mundipharma Pvt. Ltd.
Modipuram – 250 110,
U.P., India
Phone: +91-121-2576214-17
Fax: +91-121-2575517

Registered by:
Modi-Mundipharma Pvt. Ltd.
1400, Modi Tower,
98, Nehru Place,
New Delhi – 110019, India.
Phone: +91-11-42504555
Fax: +91-11-26451659

8.0 Marketing authorization number

Rwanda FDA-HMP-MA-1117

9.0 Date of first authorization/renewal of the authorization

29/02/2024

10.0 Date of (partial) revision of the text

May 2024