1.3.1 Summary of Product Characteristics (SmPC)

1. Name of Medicinal Product

MAXIRON

FERROUS FUMARATE WITH FOLIC ACID AND VITAMIN B12 CAPSULES

2. Qualitative and Quantitative Composition

2.1. Qualitative declaration:

Composition of the Drug product:

Each hard gelatin capsule contains:

Ferrous Fumarate BP…….. 200mg

Folic Acid BP ……..1mg

Vitamin B12 BP ……..10 mcg

Excipients …… Q.S.

Approved colours used in empty capsule shell.

Qualitative & Quantitative Composition Formula:

Batch Size: 1, 00,000 CAPSULES

Sr. No.	Name of Raw Material	Spec	Label claim / Tab	Qty per Tablet (mg)	% Overage	Qty per Tablet with Overages (mg)	Std. Qty for 1.0 Lac (kg)	Reason for inclusion
1.	Ferrous Fumarate*	BP	200 mg	200.00	4.0 %	208.00	20.8	active
2.	Folic Acid*	BP	1.00 mg	1.000	40.0 %	1.400	0.14	active
3.	Vitamin B12* (0.1 % Gelatin Base)	BP	10 mcg	10.00 mcg	35.0 %	13.500	1.35	active
4.	Dibasic Calcium Phosphate (anhydrous)	BP		175.00	---	175.000	17.5	Diluent
5.	Purified Talc	BP		170.100	---	170.100	17.01	glidant
6.	Magnesium stearate	BP		7.000	---	7.000	0.7	lubricant
7.	Colloidal Anhydrous Silica	BP		5.000	--	5.000	0.5	adsorbent

8.	Empty hard gelatin capsule size ‘’0” (Red/Red coloured printed "MAXIRON")	IH		1 NO.	3.0 %	1.03	103000	Empty shells
	TOTAL					**580.0 mg**	**58.00 kg**	

* Overages added for stability purpose.

3. Pharmaceutical form

Hard Gelatin Tablet

Scarlet Red/ Scarlet Red colour hard gelatin capsule size “0” printed “MAXIRON” which containing brown coloured powder.

4. Clinical particulars

4.1 Therapeutic indications

Ferrous Fumarate, Folic Acid and Vitamin B12 Capsule for all types of Anaemia due to

Iron Deficiency

Lack of Appetite

Convalescence

Run Down conditions

Weakness

Paleness

During Pregnancy & lactation.

4.2 Posology and method of administration

Adults and the Elderly

One capsule daily, preferably taken one hour after meals. Do not exceed the stated dose. The capsule should be swallowed whole with water.

Children under 12 years of age

Ferrous Fumarate, Folic Acid and Vitamin B12 Capsules are not recommended for this age group.

Method of administration: Oral use.

Should be administered with water or juice on an empty stomach. Administer 2 hours prior to or 4 hours after antacids.

4.3 Contraindications

Hypercalcaemia, hemochromatosis and other iron storage disorders.

Hypersensitivity to the active substance(s) or to any of the excipients.

Concurrent admin may reduce the efficacy of fluoroquinolones, levodopa, carbidopa, thyroxine and bisphosphonates. Iron may reduce the absorption of penicillamine by forming complexes.

Concurrent admin with tetracycline may lead to reduced absorption of tetracycline and iron.

Antacids may reduce the absorption of iron. Serum levels of anticonvulsants may be reduced by folic acid.

4.4 Special warnings and precautions for use

Avoid use in patients with active peptic ulcer, repeated blood transfusion, regional enteritis and ulcerative colitis. Caution when used in patients with folate-dependent tumours. Not recommended for use during 1st trimester of pregnancy.

Whilst taking MAXIRON Capsules both protein and energy are also required to provide complete nutrition in the daily diet. No other vitamins, minerals or supplements with or without vitamin A should be taken with this preparation except under medical supervision.

Do not take MAXIRON Capsules on an empty stomach. Do not exceed the stated dose. Keep out of the reach of children. If symptoms persist, consult your doctor.

Important warning: Contains iron. Keep out of the reach and sight of children, as overdose may be fatal. An allowance should be made for vitamins or minerals obtained from other sources.

4.5 Interaction with other medicinal products and other forms of interaction

Hypercalcaemia, hemochromatosis and other iron storage disorders. Hypersensitivity to the active substance(s) or to any of the excipients.

Concurrent admin may reduce the efficacy of fluoroquinolones, levodopa, carbidopa, thyroxine and bisphosphonates. Iron may reduce the absorption of penicillamine by forming complexes. Concurrent admin with tetracycline may lead to reduced absorption of tetracycline and iron. Antacids may reduce the absorption of iron. Serum levels of anticonvulsants may be reduced by folic acid.

4.6 Fertility, pregnancy and lactation

Pregnancy

MAXIRON Capsules may be administered during pregnancy and lactation at the recommendation of the physician.

It is recommended that pregnant women meet the dietary requirements of iron with diet and/or supplements in order to prevent adverse events associated with iron deficiency anemia in pregnancy. Treatment of iron deficiency anemia in pregnant women is the same as in nonpregnant women and in most cases, oral iron preparations may be used. Except in severe cases of maternal anemia, the fetus achieves normal iron stores regardless of maternal concentrations.

Breast-feeding

Enters breast milk.

Fertility

Iron is normally found in breast milk. Breast milk or iron-fortified formulas generally provide enough iron to meet the recommended dietary requirements of infants. The amount of iron in breast milk is generally not influenced by maternal iron status.

4.7 Effects on ability to drive and use machines

None anticipated

4.8 Undesirable effects

Undesirable effects are listed as System Organ Classes. Assessment of undesirable effects is based on the following frequency groupings: Very common: ≥1/10 Common: ≥1/100 to <1/10 Uncommon: ≥1/1,000 to <1/100 Rare: ≥1/10,000 to <1/1,000 Very rare: <1/10,000 Not known: cannot be estimated from the available data

Immune system disorders	Not known: Hypersensitivity reaction (such as rash)
Gastrointestinal disorders	Not known: Gastrointestinal disturbances (such as nausea, vomiting and abdominal pain)

4.9 Overdose

No cases of over dosage due to MAXIRON therapy have been reported. Any symptoms which may be observed due to the ingestion of large quantities of MAXIRON capsules will be due to the fat soluble vitamin content. If iron over dosage is suspected, symptoms may include nausea, vomiting, diarrhoea, abdominal pain, haematemesis, rectal bleeding, lethargy and circulatory collapse. Hyperglycaemia and metabolic acidosis may also occur. Treatment should be implemented immediately. In severe cases, after a latent phase, relapse may occur after 24 - 48 hours, manifest by hypotension coma and hepatocellular necrosis and renal failure. Treatment:

The following steps are recommended to minimise or prevent further absorption of the medication:

1. Administer an emetic.

2. Gastric lavage may be necessary to remove drug already released into the stomach. This should be undertaken using desferrioxamine solution (2 g/l). Desferrioxamine 5 g in 50 - 100 ml water should be introduced into the stomach following gastric emptying. Keep the patient under constant surveillance to detect possible aspiration of vomitus; maintain suction apparatus and standby emergency oxygen in case of need.

3. A drink of mannitol or sorbitol should be given to induce small bowel emptying.

4. Severe poisoning: in the presence of shock and/or coma with high serum iron levels (>142 μmol/l) immediate supportive measures plus i.v. Infusion of desferrioxamine should be instituted. The recommended dose of desferrioxamine is 5 mg/kg/h by slow i.v. infusion up to a maximum of 80 mg/kg/24 hours. Warning: hypotension may occur if the infusion rate is too rapid.

5. Less severe poisoning: i.m. desferrioxamine 50 mg/kg up to a maximum dose of 4 g should be given.

6. Serum iron levels should be monitored throughout.

7. Any fluid or electrolyte imbalance should be corrected.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Ferrous Fumarate:

Ferrous Fumarate, as a constituent of hemoglobin, plays an essential role in oxygen transport. It is also present in the muscle protein myoglobin and in the liver. Deficiency of iron leads to anaemia.

Folic Acid:

Folic acid is reduced in the body to tetrahydrofolate which is a co-enzyme for various metabolic processes, including the synthesis of purine and pyrimidine nucleotides and hence in the synthesis of DNA. It is also involved in some amino acid conversion and in the formation and utilisation of formate. Deficiency of folic acid leads to megaloblastic anaemia.

Vitamin B12 (Cyanocobalamin):

Vitamin B12 is present in the body mainly as methylcobalamin and as adenosylcobalamin and hydroxocobalamin. These act as co-enzymes in the trans methylation of homocysteine to methionine; in the isomerization of methylmalonyl co-enzyme to succinyl co-enzyme and with folate in several metabolic pathways respectively. Deficiency of Vitamin B12 interferes with haemopoiesis and produces megaloblastic anemia.

5.2 Pharmacokinetic properties

Ferrous Fumarate (Iron):

Iron is absorbed chiefly in the duodenum and jejunum. Absorption is aided by the acid secretion of the stomach and if the iron is in the ferrous state as in ferrous fumarate. In conditions of iron deficiency, absorption is increased and, conversely, it is decreased in iron overload. Iron is stored as ferritin. Mainly excreted through the faeces and desquamation of cells e.g. Skin, hair or GI mucosa. Folic acid and Vitamin B12 mainly excreted in the urine.

Folic Acid:

Folic acid is absorbed mainly from the proximal part of the small intestine. Folate polyglutamates are considered to be deconjugated to monoglutamates during absorption. Folic acid rapidly appears in the blood where it is extensively bound to plasma proteins. Largely

metabolized in the liver. Some folic acid is distributed in body tissues, some is excreted as folate in the urine and some is stored in the liver as folate.

Vitamin B12 (Cyanocobalamin):

Cyanocobalamin is absorbed from the gastro-intestinal tract and is extensively bound to specific plasma proteins. A study with labelled Vitamin B12 showed it was quickly taken up by the intestinal mucosa and held there for 2 - 3 hours. Peak concentrations in the blood and tissues did not occur until 8 - 12 hours after dosage with maximum concentrations in the liver within 24 hours. Peak plasma concentrations after 3 hr (oral); 0.9 hr (IM); 3 min (IV). Cyanocobalamins are stored in the liver, excreted in the bile and undergo enterohepatic recycling. Part of a dose is excreted in the urine, most of it in the first eight hours.

5.3 Preclinical safety data

No relevant data.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sr. No.	Ingredients Name	Specification
1.	Di-Basic Calcium Phosphate	BP
2.	Purified Talc	BP
3.	Magnesium Stearate	BP
4.	Colloidal Anhydrous Silica	BP
5.	Empty hard gelatin capsule size ‘’0” (Red/Red coloured printed "MAXIRON")	IH

6.2 Incompatibilities: Not Applicable

6.3 Shelf-life: 36 Months

6.4 Special precautions for storage:

Store in a dark, dry place, Not exceeding 30℃ temp.

6.5 Nature and contents of container:

Pack Style: 3 x 10 Blister Pack

Primary Packing: 10 Capsules are packed in Blister Pack

Secondary Packing: 3 Blister Pack is packed in a carton along with package insert.

6.6 Special precautions for disposal and other handling

No special instructions for use/handling

7. Marketing Authorization Holder:

SAM PHARMACEUTICALS LIMITED,

8/9, Oyadiran Estate,

Sabo, Yaba-Lagos, Nigeria.

8. Marketing Authorization Number (s):

Product license / registration Number (s)

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9. Manufacturer Name:

SWISS PHARMA PVT. LTD.

3709, G.I.D.C. Phase IV, Vatva,

Ahmedabad –382445, India

www.swisspharma.in

10. Date of first authorization/renewal of the authorization:

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11. Date of revision of the text:
