SUMMARY OF PRODUCT CHARACTERISTICS

1. **Name of the medicinal product**

Me Cure's Blood Tone (Ferrous Sulphate 200mg)

2. **Qualitative and quantitative composition**

Ferrous Sulphate BP 200mg:

Each sugar coated tablet contains Ferrous Sulphate BP 200mg equivalent to 65mg elemental iron

For the full list of excipients, see section 6.1.

3. **Pharmaceutical form**

Sugar-coated tablet

Red coloured circular biconvex sugar coated tablet.

4.0 Clinical particulars

4.1 Therapeutic indications

For the prevention and treatment of iron-deficiency anaemias. .

4.2 Posology and method of administration

Dosage:

Adults & Children over 12 years:
Treatment: One tablet 3 times daily
Prophylaxis: One tablet daily

Blood tone is administered by mouth.

4.3 Contraindications

• Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

• Paroxysmal nocturnal haemoglobinuria.

• Haemosiderosis and haemochromatosis.

• Active peptic ulcer.

• Patients receiving repeated blood transfusions.

• Regional enteritis and ulcerative colitis.

• Haemolytic anaemia

• Oral and parenteral iron preparations should not be used concomitantly.

4.4 Special warnings and precautions for use

Some post-gastrectomy patients show poor absorption of iron.

Administer with caution in patients with haemoglobinopathies, iron-storage or iron-absorption diseases, existing gastrointestinal disease.

Caution is advised when prescribing iron preparations to individuals with history of peptic ulcer, and inflammatory bowel disease, including regional enteritis and ulcerative colitis. Care should be taken in patients with intestinal strictures or diverticulae. Duration of treatment should generally not exceed 3 months after correction of anaemia.

Dental caries is a definite risk following long term treatment with this product.

Due to the risk of mouth ulcerations and tooth discolouration, tablets should not be sucked, chewed or kept in the mouth, but swallowed whole with water.

These tablets contain sugar and should be administered with care to patients with diabetes.

Patients suffering from iron overload are particularly susceptible to infection. Treatment of iron overload should be with caution.

Co-existing deficiency of vitamin B12 or folic acid should be ruled out since combined deficiency produces microcytic blood film.

Aspiration of iron sulfate tablets can cause necrosis of the bronchial mucosa which may result in coughing, haemoptysis, bronchostenosis and/or pulmonary infection (even if aspiration happened days to months before these symptoms occurred). Elderly patients and patients who have difficulties swallowing should only be treated with iron sulfate tablets after a careful evaluation of the individual patient's risk of aspiration. Alternative formulations should be considered. Patients should seek medical attention in case of suspected aspiration.

The label will state

"Important warning: Contains iron. Keep out of the sight and reach of children, as overdose may be fatal".

This will appear on the front of the pack within a rectangle in which there is no other information.

Ferrous Sulfate tablets contain glucose, sucrose and lactose

Patients with rare hereditary problems of galactose intolerance or fructose intolerance, total lactase deficiency or glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

If you use other drugs or over the counter products at the same time, the effects of Blood Tone may change. This may increase your risk for side-effects or cause your drug not to work properly. Tell your doctor about all the drugs, vitamins, and herbal supplements you are using, so that you doctor can help you prevent or manage drug interactions.

4.6 Fertility, pregnancy and lactation

Pregnancy

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

4.7 Effects on ability to drive and use machines

None Known.

4.8 Undesirable effects

Get emergency medical help if you have **s**igns of an allergic reaction**:** hives; difficult breathing; swelling of your face, lips, tongue, or throat.

Call your doctor at once if you have:

severe stomach problems (pain, vomiting, diarrhea); or high potassium--nausea, weakness, tingly feeling, chest pain, irregular heartbeats, loss of movement. Common side effects may include: diarrhea, constipation, darker color in your bowel movements, nausea, vomiting, stomach pain; or cough.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions.

4.9 Overdose

Do not use more than prescribed dose. Taking more medication will not improve your symptoms; rather they may cause poisoning or serious side-effects

Do not give your medicines to other people even if you know that they have the same condition or it seems that they may have similar conditions. This may lead to overdosage.

5.0 Pharmacological properties

5.1 Pharmacodynamic properties

ATC CODE: B03A A07

Ferrous sulfate is used in the treatment of iron deficiency anaemias.

Iron preparations have no intrinsic therapeutic activity except as a nutrient source: their use without evidence of iron deficiency, or reasonable expectation of its occurrence, is to be deprecated. Iron, in excess, is toxic and haemochromatosis may result from chronic injection of iron preparations used as tonics, especially in individuals with undiagnosed blood disorders. Patients with chronic anaemia are particularly at risk from iron storage disease. Recently a severe iron overload myopathy has been described in patients given prophylactic iron indiscriminately while receiving haemodialysis. Genetic factors probably contribute to the risk of iron overload.

It should be clear that although iron deficiency is readily treated, its detection does not constitute a complete diagnosis. Every effort should be made to determine why the patient has entered a state of negative iron balance. Attention should be given to hidden sources of haemorrhage (which may indicate serious urinary or gastrointestinal conditions) and also the possibility of malabsorption of iron caused by latent disease of the small intestine.

5.2 Pharmacokinetic properties

Iron is irregularly and incompletely absorbed from the gastrointestinal tract, the main sites of absorption being the duodenum and jejunum. Absorption is aided by the acid secretion of the stomach or by dietary acids and is more readily effected when the iron is in the ferrous state or is part of the haem complex (haem-iron). Absorption is also increased in conditions of iron deficiency or in the fasting state but is decreased if the body stores are overloaded. Only about 5-15% of the iron ingested in food is normally absorbed.

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5.3 Preclinical safety data

There are no other preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6.0 Pharmaceutical particulars

6.1.List of excipients
Dried ferrous sulphate, starch, Methyl Paraben, Propyl Paraben,Talcum, Magnesium Stearate, Aerosil,
Sugar Coating: Sugar, Talcum, Calcium carbonate, Gelatin, IPA, Titanium Dioxide, colour ponceu 4R, Bees Wax, Carnuba wax, methylene chloride

6.2 Incompatibilities

None

6.3 Shelf life

3 years

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

Store this medicine at temperature below 30^0C and keep away from children.

6.5 Nature and contents of container

2 X 50 Blister pack; Jar pack of 1000 tablets .

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7.0 Marketing authorization holder

Me Cure Industries Limited
Plot 6 Block H Debo Industries Compound,
Oshodi Industrial Scheme,
Oshodi,
Lagos,
Nigeria.

8.0 **Marketing Authorisation Number**
NAFDAC NO: 04-9611