BIORAJ PHARMACEUTICALS LIMITED	
BRAND NAME: BIOTONIC CAPSULE	**GENERIC NAME:** Ferrous Fumarate BP…….50mg (Equivalent to elemental iron 16mg)
SUMMARY OF PRODUCT CHARACTERISTICS	

1. NAME OF THE MEDICINAL PRODUCT

Biotonic Capsules.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

Ferrous Fumarate BP…….50mg

(Equivalent to elemental iron 16mg)

Folic Acid BP……2mg

Vitamin B12 BP ……...5mcg

Vitamin A USP……...1000I.U.

Vitamin C BP……30mg

Vitamin E USP…….3mg

Vitamin B1 BP……..1mg

Vitamin B2 BP……..1.5mg

Vitamin B6 BP……..1.5mg

Nicotinamide BP……...10mg

Magnesium Oxide BP……...50mg

Zinc Sulphate BP……...5mg

Excipients……...q.s

(Overages of vitamins added to compensate for any loss on storage)

3. PHARMACEUTICAL FORM

Capsule.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Biotonic is indicated in the following:

In the therapeutic and prophylaxis treatment of iron deficiency and nutritional deficiency anaemia, anaemia due to blood loss during delivery, surgery, menstrual disorders, bleeding piles and accidents, anaemia caused by febrile illness like malaria and typhoid fever e.t.c.

For the treatment of general tiredness, weakness and loss of appetite.

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4.2 Posology and method of administration

Therapeutic: One capsule twice daily for 30 days.

Prophylaxis: One capsule daily for 30 days.

4.3 Contraindications

(i) Hypersensitivity to the product or ingredients.

(ii) Haemosiderosis and haemochromatosis.

(iii) Active peptic ulcer.

(iv) Repeated blood transfusion.

(v) Inflammatory bowel disease, including regional enteritis and ulcerative colitis, intestinal strictures and diverticulae

(vi) Anaemias other than those due to iron deficiency.

(vii) Haemoglobinopathies

(viii) Concomitant use with parenteral iron

(ix) Concomitant use with dimercaprol

4.4 Special warnings and precautions for use

(i) Patients post-gastrectomy have poor absorption of iron.

(ii) Caution is advised when prescribing iron preparations to individuals with history of peptic ulcer.

(iii) Duration of treatment should generally not exceed 3 months after correction of anaemia.

(iv) Co-existing deficiency of vitamin B12 or folic acid should be ruled out since combined deficiencies produce microcytic blood film.

(v) Iron deficiency in a male patient warrants careful investigation to determine its cause which forms the basis of primary treatment.

(vi) Iron preparations colour the faeces black, which may interfere with tests used for detection of occult blood in the stools.

(vii) Prolonged or excessive use in children without medical supervision may lead to toxic accumulation

The label will state:

"Important warning: Contains iron. Keep out of reach and sight 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.

4.5 Interaction with other medicinal products and other forms of interaction

(i) Iron and tetracyclines reduce the absorption of each other. Iron reduces absorption of zinc, and absorption of oral iron is reduced by zinc.

(ii) Iron reduces the absorption of penicillamine, fluoroquinolones, levodopa, carbidopa, entacapone, bisphosphonates, and levothyroxine.

(iii) Absorption of iron is reduced with calcium, magnesium and other mineral supplements, bicarbonates, carbonates, zinc and trientine and impaired by antacids, cholestyramine, tea, eggs or milk, but may be increased by ascorbic or citric acid.

(iv) Chloramphenicol delays plasma iron clearance, incorporation of iron into red blood cells and interferes with erythropoiesis.

(v) Reduced hypotensive effect of methyldopa.

4.6 Fertility, pregnancy and lactation

Pregnant women also need to take folic acid.

Administration of drugs during the first trimester of pregnancy requires careful assessment of the potential risks versus the benefits to be gained and should not be administered unless clearly indicated. For the remainder of the pregnancy, iron therapy may be indicated but only on the advice of a physician.

No adverse effects of ferrous fumarate have been shown in breastfed infants of treated mothers. Ferrous fumarate can be used during breast-feeding if clinically indicated.

4.7 Effects on ability to drive and use machines

Biotonic Capsules do not affect the ability to drive or operate machinery.

4.8 Undesirable effects

Anorexia, nausea, vomiting, gastro-intestinal discomfort, constipation, diarrhoea, dark stools and allergic reactions. These side-effects may be minimised by taking the capsules after food. Iron preparations can be particularly constipating in older patients and occasionally lead to faecal impaction. Iron preparations can also exacerbate diarrhoea in patients with inflammatory bowel disease; care should be taken with patients who have intestinal strictures or diverticular disease.

Haemosiderosis may occur as a result of excessive or mistaken therapy.

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 via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Iron overdosage is an acute emergency requiring urgent medical attention. An acute intake of 75mg/kg of elemental iron is considered extremely dangerous in young children.

Symptom:

Initial symptoms of iron overdosage include nausea, vomiting, diarrhoea, abdominal pain, haematemesis, rectal bleeding, lethargy and circulatory collapse. Hyperglycemia and metabolic acidosis may occur. However, if overdosage is suspected, treatment should be implemented immediately. In severe cases, after a latent phase, relapse may occur after 24-48 hours manifested by hypotension, coma, hypothermia, hepatocellular necrosis, renal failure, pulmonary oedema, diffuse vascular congestion, coagulopathy and/or convulsions. In many cases, full recovery may be complicated by long-term effects such as hepatic necrosis, toxic encephalitis, CNS damage and pyloric stenosis.

Treatment:

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

Children:

1. Administer an emetic such as syrup of ipecac.

2. Emesis should be followed by gastric lavage with desferrioxamine solution (2g/1). This should then be followed by the installation of desferrioxamine 5g in 50-100ml water, to be retained in the stomach. Inducing diarrhoea in children may be dangerous and should not be undertaken in young children. Keep the patient under constant surveillance to detect possible aspiration of vomitus - maintain suction apparatus and standby emergency oxygen in case of need.

3. Severe poisoning:

In the presence of shock and/or coma with high serum iron levels (serum iron > 90umol/1) immediate supportive measure plus IV infusion of desferrioxamine should be instituted. Desferrioxamine 1 5mg/kg body weight should be administered every hour by slow IV infusion to a maximum 80mg/kg/24 hours.

Warning:

Hypotension may occur if the infusion rate is too rapid.

4. Less severe poisoning: i/m desferrioxamine 1g 4-6-hourly is recommended.

5. Serum iron levels should be monitored throughout.

Adults:

1. Administer an emetic.

2. Gastric lavage may be necessary to remove drug already released into the stomach. This should be undertaken using a desferrioxamine solution (2g/1).

Desferrioxamine 5g in 50-100ml water should be introduced into the stomach following gastric emptying. Keep the patients 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 (>142umol/1) immediate supportive measures plus IV infusion of desferrioxamine should be instituted. The recommended dose of desferrioxamine is 5mg/kg/h by a slow IV infusion up to a maximum of 80mg/kg/24 hours.

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Warning:

Hypotension may occur if the infusion rate is too rapid.

5. Less severe poisoning:

i.m. deferrioxamine 50mg/kg up to a maximum dose of 4g should be given.

6. Serum iron levels should be monitored throughout.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Iron is a haematinic essential for satisfactory erythropoiesis during haemoglobin synthesis.

5.2 Pharmacokinetic properties

Absorption of iron is a complicated process. Iron is absorbed throughout the GI tract but it is greatest in the duodenum and proximal jejunum.

Approximately 5-10% of dietary iron is absorbed during prophylaxis and 10-30% in iron deficient subjects. Ferrous ion is easily absorbed compared to ferric ion. Transfer of iron across the placenta is an active process. Excess iron ingested is stored as ferritin and haemosiderin.

5.3 Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Folic Acid

Vitamin B1

Vitamin B2 Plain

Vitamin B6

Vitamin B12

Vitamin E

Ascorbic Acid

Nicotinamide

Zinc Sulphate

Magnesium Oxide

Lactose

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6.2 Incompatibilities

None stated.

6.3 Shelf life

36 month

6.4 Special precautions for storage

Store below 30^{o}C.

Keep away from sunlight and moisture.

Keep out of reach of children.

6.5 Nature and contents of container

PVC - Aluminium foil blisters.

Pack size: 10 x 12 capsules.

6.6 Special precautions for disposal and other handling

None stated.

7.0 MANUFACTURER

Bioraj Pharmaceuticals Limited

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