To be used by registered medical practitioner or laboratory only.

R.B.TONE
SYRUP

COMPOSITION:
Each 5 ml contains:

Ferrous Gluconate BP	129.5 mg
(Equivalent to 15 mg elemental iron)	
Folic Acid BP	0.25 mg
Calcium lactate BP	75 mg
(Equivalent to 13.5 mg elemental Calcium)	
Vitamin B_{12} BP	1.25 mcg

Colour: Caramel

PRODUCT DESCRIPTION:
Amber coloured, sweet syrupy liquid with fruity flavour.

INDICATION:
Dietary Supplement

RECOMMENDED DOSAGE:
Adults: 5 ml once daily after meals.
Pregnancy: 10 ml once daily.

MODE OF ADMINISTRATION:
R. B. Tone Syrup is supplied as nutritional supplement / food supplement for oral administration. It should be taken after meals.

PREGNANCY AND LACTATION:
It is recommended in the Pregnancy and Lactation due to increase in the body requirement of Iron and Calcium in pregnancy.

SIDE EFFECTS:
Heartburn, nausea and vomiting, upper gastric discomfort, constipation or diarrhoea may occur in patients sensitive to iron preparations. Side-effects may be reduced by administration with or after food. Ferrous gluconate may cause blackening of stools.

DRUG INTERACTIONS:
Aminosalicylate may impair the absorption of Vitamin B_{12} from the gastrointestinal tract and the requirements of the vitamin may be increased in patients receiving aminosalicylate.
Chloramphenicol may delay the response of anemia to Iron or Vitamin B_{12}. Iron salts interfere with the uptake of **penicillamine**. Hence the effect of penicillamine might be diminished.
Tetracycline's and **Antacids** form insoluble complexes with ferrous salts.

OVERDOSAGE:
Patient who receives an overdose should be carefully observed and given supportive treatment. Dosage in excess of iron needs may lead to accumulation of iron in iron storage sites and hemosiderosis. Periodic monitoring of laboratory parameters of iron stores may assist in recognition of iron accumulation serum iron levels > 300 mcg/dl [combined with transferrin over saturation] may indicate iron poisoning which is characterized by abdominal pain, nausea, vomiting, diarrhoea, watery stools, melena, hematemesis, hypotension, tachycardia, metabolic acidosis, hyperglycemia, dehydration, drowsiness, pallor, cyanosis, lassitude, seizures, shock and coma. The pathological lesion is hemorrhage and inflammation in gut, hepatic neurosis and brain damage.

Treatment for Overdosage:
The stomach should be emptied by gastric lavage. It should be prompt and given supportive treatment. Induce vomiting or perform gastric lavage with sodium bicarbonate solution to render iron insoluble.
Apart from supportive measures, des-ferrioxamine (an iron-specific chelating agent, 1 g of which will bind with 85 mg of elemental iron) is used. It can be administered both orally, to bind with iron in the gastrointestinal tract and decrease its absorption, and intravenously to bind with free iron to form a soluble complex which is readily excreted via the kidneys.
Gastric lavage is performed using a desferrioxamine solution (e.g. 2 g in 1 litre of water). After the lavage is completed, 5 g of desferrioxamine in 50 mL of water is left in the stomach. If mild iron toxicity is suspected then desferrioxamine is infused at 5 mg/kg/hr for 16 hours. If severe iron toxicity is suspected then desferrioxamine is infused at 15 mg/kg/hr for no longer than 24 hr as an infusion of desferrioxamine for longer periods may cause acute respiratory distress syndrome. Therapy should be continued until the 'vin rose' colouring of the urine clears, until the patient is free of symptoms, or until plasma iron levels are satisfactory.
Alternatively DTPA or calcium edetate may be used if desferrioxamine is not available.

WARNINGS:
Avoid overdosage. Keep out of the reach of children.

CONTRAINDICATIONS:
Known hypersensitivity to any of the ingredients.
Iron intolerance.
Haemochromatosis and Hemosiderosis.

STORAGE:
Store at a temperature not exceeding 30° C.

SHELF-LIFE:
24 months from the date of manufacture.

PRESENTATION:
A box containing 200 ml amber coloured bottle along with pack insert.

DATE OF REVISION: December 2009

Manufactured by :
MEDLEY
PHARMACEUTICALS LTD.
19 & 19, Zari Causeway Rd, Kachigam, Daman, INDIA
Regd. Office : Medley House, 52, MIDC Area
Andheri (East), Mumbai - 400 093, INDIA

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[redacted]

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SYRUP

[redacted]

SAME SIZE DESIGN, SIZE: 210 x 137 MM