SCHEDULING STATUS: **S0**

PROPRIETARY NAME

(AND DOSAGE FORM): **BIDOMAK® Fe TONIC**

COMPOSITION:

Each 30 ml contains:

Ferrous sulphate anhydrous	40,817 mg
Calcium glycerophosphate	33 mg
Sodium glycerophosphate	33 mg
Potassium glycerophosphate	33 mg
Calcium lactate	570 mg
Sodium benzoate (as preservative)	0,2 %m/v

Contains sugar: Dextrose 1,359 g

Sucrose 4,8 g

List of excipients:

Amaranth substitute F1127 (colour red F1127), Caramel 48000 (Clarks), phosphoric acid 85%, saccharin sodium (soluble), sodium cyclamate, vanillin red band 100%

PHARMACOLOGICAL CLASSIFICATION:

A 32.1 Tonics

PHARMACOLOGICAL ACTION:

BIDOMAK Fe is a tonic.

INDICATIONS:

A tonic.

CONTRAINDICATIONS:

Hypersensitivity to any of the ingredients contained in the product.

Not to be taken concomitantly with tetracyclines **(see Interactions)**.

BIDOMAK Fe tonic should not be given to patients receiving repeated blood transfusions or to patients with anaemias not produced by iron deficiency unless iron deficiency is also present.

Use of this product should be avoided in patients with calcium renal calculi, or a history of renal calculi.

WARNINGS AND SPECIAL PRECAUTIONS:

Warnings:

BIDOMAK Fe tonic must be stored out of reach of children to guard against iron poisoning. Overdoses of ingested iron can be fatal especially in small children. Serious poisoning may result in small children from ingestion of 200 mg of elemental iron.

BIDOMAK Fe tonic should be well diluted with water **(see Dosage and Directions for Use)** and swallowed through a straw to prevent discolouration of the teeth.

Special Precautions:

BIDOMAK Fe tonic must be administered with caution to patients with the following:

Renal impairment, diseases associated with hypercalcaemia (e.g. sarcoidosis, some malignancies), cardiac disease (hypertension, heart failure), peripheral or pulmonary oedema, pre-eclampsia, conditions associated with sodium retention, conditions predisposing to hyperkalaemia (e.g. adrenocortical insufficiency), acute dehydration and extensive tissue damage as occurs with severe burns).

BIDOMAK Fe tonic should also not be given to patients receiving repeated blood transfusions or to patients with anaemias not produced by iron deficiency unless iron deficiency is also present. Oral and parenteral iron therapy should not be used together. Care should be taken in patients with iron-storage or iron-absorption diseases such as haemochromatosis, haemoglobinopathies, or existing gastrointestinal diseases such as inflammatory bowel disease, intestinal structures and diverticulae.

Calcium containing products like **BIDOMAK Fe** tonic should be given cautiously to patients with renal impairment.

INTERACTIONS:

Antacids: Absorption of iron salts is decreased in the presence of antacids.

Fluoroquinolones: Iron may reduce absorption of fluoroquinolones by chelation, resulting in lower serum and urine concentrations of fluoroquinolones; fluoroquinolones should be taken at least 2 hours before or 2 hours after **BIDOMAK Fe** tonic.

Tetracyclines: Concurrent use with iron and calcium reduces absorbability and the resultant therapeutic effects of oral tetracyclines; patients should be advised to take **BIDOMAK Fe** tonic 2 hours after tetracyclines.

Phenytoin: Concurrent use decreases the bioavailability of both phenytoin and calcium because of possible formation of a nonabsorbable complex; patients should be advised not take **BIDOMAK Fe** tonic within 1 to 3 hours of taking phenytoin; also, enteral feeding solutions containing calcium should not be administered through nasogastric feeding tube together with phenytoin oral suspension; a 2-hour interval should elapse between the administration of the feeding solution and of the phenytoin.

HUMAN REPRODUCTION:

Problems in humans have not been documented with intake of normal daily recommended amounts.

DOSAGE AND DIRECTIONS FOR USE:

DO NOT EXCEED THE RECOMMENDED DOSE

This medicine should be taken with or immediately after food.

Adults:	2 medicine measures (10 ml) in a quarter of a glass of water three times a day before or after meals.
Children over 5 years:	1 - 2 medicine measures (5 - 10 ml) in a quarter of a glass of water three times a day before or after meals.

SIDE-EFFECTS:

Gastrointestinal disorders:

Frequent: Abdominal pain or stomach pain, diarrhoea, vomiting, nausea, constipation.

Less frequent: Heartburn.

Side-effects have been reported but frequency is unknown: Gastrointestinal discomfort.

General disorders and administration site conditions:

Less frequent: Staining of the teeth, darkening of the urine.

Metabolism and nutrition disorders:

Less frequent: Hypercalcaemia, usually in patients with renal failure.

Early symptoms of hypercalcaemia include constipation; severe dryness of mouth; headache, continuing; increased thirst; irritability; loss of appetite; mental depression; metallic taste; unusual tiredness or weakness.

Late symptoms of hypercalcaemia include confusion; drowsiness; high blood pressure; increased sensitivity of eyes or skin to light; especially in haemodialysis patients; irregular, fast, or slow heartbeat; nausea and vomiting; unusually large amount of urine or increased frequency of urination.

KNOWN SYMPTOMS OF OVER-DOSAGE AND PARTICULARS OF ITS TREATMENT:

Signs and symptoms of iron overdosage:

Acute iron overdosage can be divided into four stages.

In the first phase, which occurs up to 6 hours after oral ingestion, gastrointestinal toxicity, notably vomiting and diarrhoea, predominates. Other effects may include cardiovascular disorders such as hypotension and tachycardia, metabolic changes including acidosis and hyperglycaemia, and CNS depression ranging from lethargy to coma. Patients with only mild to moderate poisoning do not generally progress past this first phase.

The second phase may occur at 6 to 24 hours after ingestion and is characterized by a temporary remission and clinical stabilisation.

In the third phase gastrointestinal toxicity recurs together with shock, metabolic acidosis, convulsions, coma, coagulation disorders, oliguria or renal failure, and pulmonary oedema.

The fourth phase may occur several weeks after ingestion and is characterised by gastrointestinal obstruction and possibly late hepatic damage.

Treatment of overdose:

In treating acute iron poisoning speed is essential to reduce absorption of iron from the gastrointestinal tract. Gastric lavage should be considered and serum–iron concentrations may be an aid to estimating

the severity of poisoning. Chelation therapy with desferrioxamine may be necessary. Other measures include the symptomatic management and therapy of metabolic and cardiovascular disorders.

IDENTIFICATION:

Dark brown solution, free from sediment with a sweet and acidic taste.

PRESENTATION:

Amber glass bottles of 100 ml, 200 ml and 350 ml fitted with white screw-on closures.

STORAGE INSTRUCTIONS:

Store at or below 25 °C. KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

P/33/161

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

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DATE OF PUBLICATION OF THE PACKAGE INSERT:

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