

# BiferaRx<sup>®</sup>

## Iron Supplement Tablets

### Rx Only

### DESCRIPTION

BiferaRx<sup>®</sup> is a prescription iron supplement. BiferaRx<sup>®</sup> is a small oval, film-coated maroon tablet, with black core, debossed and bisected with "68|85" on one side, and plain on the other.

### Each BiferaRx<sup>®</sup> tablet contains:

#### VITAMINS

Folic Acid ..... 1 mg  
B<sub>12</sub> (as cyanocobalamin) ..... 25 mcg

#### MINERALS

Iron ..... 28 mg  
(as PIC - polysaccharide iron complex)  
(as HIP - heme iron polypeptide as  
Proferrin<sup>®</sup>\* - bovine source, USDA certified)

#### OTHER INGREDIENTS

Microcrystalline cellulose, dibasic calcium phosphate, crospovidone, magnesium stearate, silicon dioxide, resin, coating (polyvinyl alcohol, hypromellose, talc, FD&C Red # 40 Aluminum Lake, polyethylene glycol, soy lecithin, titanium dioxide, FD&C Blue # 2 Aluminum Lake).

#### INDICATIONS AND USAGE

BiferaRx<sup>®</sup> is a prescription iron supplement indicated for use in improving the nutritional status of iron deficiency.

#### CONTRAINDICATIONS

This product is contraindicated in patients with a known hypersensitivity to any of the ingredients. Hemochromatosis and hemosiderosis are contraindications to iron therapy.

**WARNING:** Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. **Keep this product out of reach of children.** In case of accidental overdose, call a doctor or poison control center immediately.

#### PRECAUTIONS

Folic acid when administered as a single agent in doses above 0.1 mg daily may obscure pernicious anemia in that hematological remission can occur while neurological manifestations remain progressive. While prescribing this nutritional supplement for pregnant women, nursing mothers, or for women prior to conception, their medical condition and other drugs, herbs, and/or supplements consumption should be considered.

#### ADVERSE REACTIONS

Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

#### DOSAGE AND ADMINISTRATION

One tablet daily with or without food or as prescribed by a licensed healthcare provider with prescribing authority.

#### HOW SUPPLIED

BiferaRx<sup>®</sup> tablets are supplied in child-resistant bottles of 90 tablets (NDC 0037-6885-90).

#### KEEP OUT OF REACH OF CHILDREN.

#### STORAGE

Store at controlled room temperature 20°-25°C (68°-77°F). Excursions permitted to 15°-30°C (59°-86°F).

Dispense in a tight, light-resistant container to protect from light and moisture.

**To report SUSPECTED ADVERSE REACTIONS, contact Meda Pharmaceuticals Inc. at 1-888-349-5556 or FDA at 1-800-FDA-1088 or [www.FDA.gov/safety/medwatch](http://www.FDA.gov/safety/medwatch).**

Distributed by:

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