

10 Reasons why You should use Integra™

Polysaccharide Iron Complex
(62.5 mg Elemental Iron)

Will replenish the Ferritin
(Stored) Iron Levels

Provides
**125 mg of
Elemental
Iron**

Ferrous Fumarate
(62.5 mg Elemental Iron)

Will replenish the Transferrin
(Circulating) Iron Levels

- ✓ 125 mg **Elemental Iron** will replenish both the ferritin (stored) and transferrin (circulating) iron levels
- ✓ Vitamin C **absorption promoter**
- ✓ One of the **smallest, easy to swallow** iron complex capsules
- ✓ Convenient **One a Day** dosing
- ✓ Provides **enhanced human immune system activity**†
- ✓ **Odorless and tasteless**
- ✓ **High tolerability**
- ✓ **Cost effective**
- ✓ **Gluten free**
- ✓ **Vcaps® capsule technology***



*Manufactured with Vcaps capsule shells that are kosher certified, Halal certified, and Vegetarian Society approved. VCAPS and the VCAPS Logo are trademarks used under license.

Made in USA in an FDA approved manufacturing facility. Please visit uspc.com for more information.

INTEGRA™

IRON / VITAMIN SUPPLEMENT CAPSULES

INTEGRA™

IRON / VITAMIN SUPPLEMENT CAPSULES

Integra
52747-0710-60
30 day supply
Sig: Take as directed

Quality
Made in USA in an FDA
approved manufacturing facility.



US Pharmaceutical Corporation
Products designed with the patient in mind.™

125 mg **Elemental Iron** will replenish both the ferritin (stored) and transferrin (circulating) iron levels

+Vitamin C absorption promoter

Provides **enhanced human immune system activity**†

Convenient
One a Day dosing

Easy to swallow, odorless
and tasteless capsules

Gluten free

Vcaps® capsule technology*

1 CAPSULE DAILY, BETWEEN MEALS, OR AS PRESCRIBED.
**ONE
1
A DAY**



INTEGRA™

IRON / VITAMIN SUPPLEMENT CAPSULES

125 mg Elemental Iron will replete both the ferritin (stored) and transferrin (circulating) iron levels
 +Vitamin C absorption promoter
 Provides enhanced human immune system activity[†]

Convenient **One a Day** dosing
 Easy to swallow, odorless and tasteless capsules
 Gluten free
 Vcaps® capsule technology*



Supplement Facts

Serving Size: 1 Capsule

	Amount Per Serving	%DV*
Ferrous Fumarate (anhydrous) (Equivalent to about 62.5 mg of Elemental Iron)	191.1 mg	
Polysaccharide Iron Complex (Equivalent to about 62.5 mg of Elemental Iron)	135.9 mg	** 694 %
Vitamin C (from ProAscorb C [†])	40 mg	66.7 %
Vitamin B ₃ (from ProAscorb C [†])	3 mg	15 %

* Percent of Daily Value †U.S. Patent No: 5,626,883

** Total Iron: Ferrous Fumarate + Polysaccharide Iron Complex

Inactive Ingredients: Hypromellose, Magnesium Stearate, Titanium Dioxide, FD&C Red #40, and FD&C Blue #1.

CLINICAL PHARMACOLOGY: Integra™ is unique in that it utilizes two (2) different forms of iron, i.e., Ferrous Fumarate and Polysaccharide Iron Complex (as cell-contracted akaganéite), making available a total of 125 mg of elemental iron per capsule as follows:

Ferrous Fumarate (anhydrous)	191.1 mg
Polysaccharide iron complex (PIC)	135.9 mg

Ferrous Fumarate: Provides about 62.5 mg of elemental iron per dose. Ferrous Fumarate is an anhydrous salt of a combination of ferrous iron and fumaric acid, containing 33% of iron per weight. The acute toxicity in experimental animals is low and Ferrous Fumarate is well tolerated clinically. As a ferrous salt, it is more efficiently absorbed in the duodenum. Iron absorption is maximal in the duodenum unlike Ferrous Sulfate, which must be protected against oxidation through coating. The Integra™ Capsule is superior to enteric coated or sustained release preparations that are apt to pass beyond the duodenum and would therefore be poorly absorbed. Ferrous Fumarate contrasts very favorably with the availability of the 20% of elemental iron of ferrous sulfate, and the 13% of elemental iron of ferrous gluconate. Calculation of Dose should be in terms of elemental iron and three doses ranging from 50-100 mg of elemental iron is usually adequate.

Polysaccharide Iron Complex: Provides about 62.5 mg elemental iron, as a cell-contracted akaganéite. It is a product of ferric iron complexed to a low molecular weight polysaccharide. This polysaccharide is produced by the extensive hydrolysis of starch and is a dark brown powder, that dissolves in water to form a very dark brown solution, which is virtually odorless and tasteless.

All Integra™ products include a unique patented source of iron, e.g. Ferrous Fumarate and Polysaccharide Iron Complex (U.S. Patent No: 11/243,043 Pending). "An increase in tolerability is observed with the (patented formulation) and is believed to occur as the result of distributing the total iron content in the composition among compounds that provide iron to the patient's blood stream via two different mechanisms. The ferrous salts are readily absorbed in the upper gut, by direct dissolution and absorption of the ferrous iron by the bloodstream. However, the iron available from PIC is absorbed in the lower gut, via an active protein transport mechanism".

Clinical Studies: Because Ferrous Fumarate is an organic complex, it contains no free ions, either ferric or ferrous. Polysaccharide Iron Complex is clinically non-toxic. Prior studies in rats demonstrated that Polysaccharide Iron Complex (PIC), when administered as a single oral dose to Sprague Dawley rats, did not produce evidence of toxicity at a dosage level of 5000 mg Iron/kg: (An Acute Oral Toxicity Study in Rats with Polysaccharide-Iron Complex. T.N.Merriman, M. Aikman and R.E. Rush, Springborn Laboratories, Inc. Spencerville, Ohio Study No. 3340.1 March - April 1994). Other clinical studies had demonstrated that Polysaccharide Iron gives a good hematopoietic response with an almost complete absence of the side effects usually associated with oral iron therapy. Picinni and Ricciotti suggested in 1982, that "the therapeutic effectiveness of Polysaccharide Iron Complex when compared with iron fumarate in the treatment of iron deficiency anemia, appears to be as active as the iron fumarate and as well tolerated, however, it exerted a greater influence on the level of hemoglobin and on the number of red cells..." and that, "it has been exceptionally well tolerated by all patients" (Picinni, L-Ricciotti, M. 1982. Therapeutic effectiveness of an iron-polysaccharide complex in comparison with iron fumarate in the treatment of iron deficiency anemias): PANMINERVA MEDICA-EUROPA MEDICA, Vol. 24, No. 3, pp. 213-220 (July-September 1982). The patented source of iron used in Integra™ (Ferrous Fumarate and Polysaccharide Iron Complex) provides a high level of elemental iron with a low incidence of gastric distress.

CONCLUSION: Based on the results of this study, the oral combination of Ferrous Fumarate and Polysaccharide Iron Complex was better tolerated and safer than the oral administration of Ferrous Fumarate alone. The conclusion of this research stated, that the addition of PIC to Ferrous Fumarate surprisingly allows the same concentration of Ferrous Fumarate to be better tolerated than the Ferrous Fumarate alone.

INDICATIONS: The treatment of iron deficiency anemia, which may occur due to an increased need for iron, a deficient intake of iron, or an excessive loss of iron.

CONTRAINDICATIONS: All iron compounds are contraindicated in patients with hemosiderosis, hemochromatosis and hemolytic anemias.

WARNING: Accidental overdose is the leading cause of fatal poisoning in children under six. Keep this and all drugs out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately.

PRECAUTIONS: Existing gastrointestinal diseases, i.e. peptic ulcers, regional enteritis, ulcerative colitis may be aggravated by causing the iron not to be absorbed and therefore, be ineffective in patients with steatorrhea or those with a partial gastrectomy. It is important to determine and treat the underlying cause of the anemia, in addition to the administration of Integra™. Indefinite administration of iron should be avoided.

SIDE EFFECTS: Gastrointestinal disturbance (anorexia, nausea, diarrhea, constipation) occur occasionally but are usually mild and subside with continuation of therapy. Although the absorption of iron is best when taken between meals, giving Integra™ after meals may diminish occasional G.I. disturbances. Integra™ is best absorbed when taken at bedtime.

OVERDOSE: Iron: Signs and Symptoms: Iron is toxic. Acute overdose of iron may cause nausea and vomiting and, in severe cases, cardiovascular collapse and death. Other symptoms include pallor and cyanosis, melena, shock, drowsiness and coma. The estimated overdose of orally ingested iron is 300-mg/kg body weight. When overdoses are ingested by children, severe reactions, including fatalities, have resulted. Integra™ should be stored beyond the reach of children to prevent against accidental iron poisoning. Keep this and all other drugs out of the reach of children.

Treatment: For specific therapy, exchange transfusion and chelating agents should be used. For general management, perform gastric lavage with sodium bicarbonate solution or milk. Administer intravenous fluids and electrolytes, and use oxygen.

DOSAGE AND ADMINISTRATION: Adults (persons over 12 years of age), One (1) capsule daily, between meals, or as prescribed by a physician. Do not exceed recommended dosage. Do not administer to children under the age of 12.

TIME AND DURATION: The hematologic response to orally administered iron is indicated by reticulocytosis of 2% to 10% depending on the severity of the anemia, beginning five to ten days after initiation of therapy. A rise in hemoglobin value is observable at the end of the second week. When therapy is adequate, hemoglobin value increases 0.1 to 0.2 gm per 100 ml of blood a day and usually becomes normal in two months. However, to improve body iron stores, treatment may be continued from 3 to 12 months, after the hemoglobin has returned to normal. If no satisfactory response is noted after three weeks of therapy, consideration should be given to (1) whether dosage recommendations have been followed, (2) blood loss is occurring simultaneously, (3) whether there are complicating causes, such as infection, defects in absorption or utilization, (4) whether diagnosis or iron-deficiency was correct.

WARNING: Do not administer to pediatric patients. Do not exceed recommended dosage. Keep this and all drugs out of reach of pediatric patients. If you are pregnant or nursing a baby, seek the advice of a health professional before using this product.

HOW SUPPLIED: Integra™ are red capsules imprinted "US" logo and "Integra" in bright yellow. Child resistant bottles of 90 capsules NDC# 52747-710-60. Dispense in a tight, light-resistant container as defined in the USP/NF with a child resistant closure. Store at room temperature between 15°-30°C (59°-86°F). Keep in cool dry place.

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