

10 Reasons why You should use Integra Plus™

Polysaccharide Iron Complex
(62.5 mg Elemental Iron)

Will replete the Ferritin
(Stored) Iron Levels

Provides
**125 mg of
Elemental
Iron**

Ferrous Fumarate
(62.5 mg Elemental Iron)

Will replete the Transferrin
(Circulating) Iron Levels

- ✓ 125 mg **Elemental Iron** will replete both the ferritin (stored) and transferrin (circulating) iron levels
- ✓ Vitamin C **absorption promoter**
- ✓ Contains **1 mg of folic acid**
- ✓ Convenient **One a Day** dosing
- ✓ Provides **enhanced human immune system activity**†
- ✓ One of the **smallest, easy to swallow** iron complex capsules
- ✓ **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.

NDC 52747-0712-60 | U.S. Patent No: 5,626,883 | CAUTION: Rx only, adults only



Pharmacy Information

Wholesaler	Available	Order Number
Amerisource Bergen	Yes	433-078
Cardinal Health	Yes	4221552
H.D. Smith Wholesale Drug	Yes	2242386
McKesson Drug Company	Yes	2535086
Morris & Dickson	Yes	978148
N.C. Mutual Wholesale Drug	Yes	723-031
Smith Drug Company	Yes	20-7688

Quality
Made in USA in an FDA
registered manufacturing facility.



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

NDC 52747-0712-60 | U.S. Patent No: 5,626,883 | CAUTION: Rx only, adults only



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

1 mg of Folic Acid

+Vitamin C absorption promoter

Provides **enhanced human immune system activity**†

Convenient **One a Day** dosing

Easy to swallow capsules

Gluten free

Vcaps® capsule technology*

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



INTEGRA PLUS™

IRON / FOLIC ACID / VITAMIN SUPPLEMENT CAPSULES

Supplement Facts

Serving Size: 1 Capsule

Amount Per Serving	%DV*	%DV**	%DV**
% Daily Value for Pregnant or Lactating Women			
ProAscorb C†	324 mg	**	**
Calcium Ascorbate, Ascorbic Acid, Ascorbyl Palmitate, Niacinamide Ascorbate, Xylitol, Sodium Ascorbate, Magnesium Ascorbate, Lysine Acetate, Citrus Bioflavonoids, Potassium Ascorbate, Sodium Pyrophosphate, D-Ribofuranose, L-Cysteine, Glutathione, Hesperidin			
Vitamin C	210 mg	350%	350%
Thiamin	5 mg	333%	294%
Riboflavin	5 mg	294%	250%
Niacin	20 mg	100%	100%
Vitamin B ₆	25 mg	1250%	1000%
Folic Acid	1000 mcg	250%	125%
Vitamin B ₁₂	10 mcg	166%	125%
Biotin	300 mcg	100%	100%
Pantothenic Acid	7 mg	70%	70%
Iron	125 mg	694%	694%
(62.5mg from Ferrous Fumarate) (62.5mg from Polysaccharide Iron Complex)			

* Percent daily value based on 2,000 calorie diet

** Daily value not established

Other Ingredients: Hypromellose, Dibasic Calcium Phosphate, Pyridoxine HCl, Niacinamide, d-calcium Pantothenate, Silicon Dioxide, Magnesium Stearate, Thiamin Mononitrate, Titanium Dioxide, FD & C Red #40, FDA/E172 Yellow Iron Oxide, FD & C Blue #1, Cyanocobalamin.

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.

You should contact your healthcare provider for medical advice about adverse events. To report a serious adverse event, contact US Pharmaceutical Corporation, P.O. Box 360465, Decatur, GA 30036.

CLINICAL PHARMACOLOGY: Integra Plus™ 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 derived from:

Ferrous Fumarate (anhydrous)	191.1 mg
Polysaccharide Iron Complex (PIC)	135.9 mg

Subclinical B-Group vitamin deficiencies have greatly increased in recent years, due to changes in dietetic habits, increase in the use of sugar, and the excessive milling of flour and cereals. With thiamine deficiencies in a healthy populous, it is self-evident that the unwell person is particularly prone to thiamine avitaminosis. This is true of the anemic individual with his/her poor appetite and disturbed digestive functions. Folic acid is best known for its role in megaloblastic anemias. Zinc has been recognized in the nutrition of animals and humans, even though the evidence for an uncomplicated zinc deficiency in humans is limited.

Ferrous Fumarate: Provides about 62.5 mg of elemental iron per dose. Ferrous Fumarate is an

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

1 mg of **Folic Acid**

+ **Vitamin C** absorption promoter

Provides **enhanced human immune system activity**†

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. 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.

Polysaccharide Iron Complex: Provides about 62.5 mg elemental iron, as 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.

Folic Acid: Folic Acid is one of the important hematopoietic agents necessary for proper regeneration of the blood-forming elements and their function. Folic acid is a precursor of a large family of compounds which serve as coenzymes in carbon transfer reactions. These reactions are required for the synthesis of purine and pyrimidine bases, inter-conversion of glycine and serine, biosynthesis of methionine methyl groups and degradation of histidine. Additionally, folic acid increases jejunal glycolytic enzymes and is involved in the desaturation and hydroxylation of long-chain fatty acids in the brain. A deficiency in folic acid results in megaloblastic anemia. 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), 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).

As mentioned above, the patented source of iron used in Integra Plus™ (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: Integra Plus™ is indicated for the treatment of iron deficiency anemia and folate deficiency as normally found in extended convalescence, menorrhagia, pregnancy, puberty,

Convenient **One a Day** dosing

Easy to swallow capsules

Gluten free

Vcaps® capsule technology*



Vcaps®
Capsules of Plant Origin
The Vegetarian Alternative™

excessive blood loss and advanced age. Also for correction of condition in which iron deficiency and vitamin C deficiency occur together, along with a deficient intake or increased need for B-Complex vitamins in chronic and acute illness, as well as cases of metabolic stress, and in convalescence.

CONTRAINDICATIONS: Integra Plus™ is contraindicated in patients with a known hypersensitivity to any of its ingredients; also, all iron compounds are contraindicated in patients with hemosiderosis, hemochromatosis, or hemolytic anemias. Pernicious anemia is a contraindication, as folic acid may obscure its signs and symptoms.

WARNING: Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where Vitamin B₁₂ is deficient.

PRECAUTIONS: General: Folic acid in doses above 0.1 mg - 0.4 mg daily may obscure pernicious anemia, in that hematological remission can occur while neurological manifestations remain progressive.

Pediatric Use: Safety and effectiveness of this product have not been established in pediatric patients.

Geriatric Use: No clinical studies have been performed in patients age 65 and over to determine whether older persons respond differently from younger persons. Dosage should always begin at the low end of the dosage scale and should consider that elderly persons may have decreased hepatic, renal, or cardiac function and/or concomitant diseases.

Adverse Reactions: Folic Acid: Allergic sensitizations have been reported following both oral and parenteral administration of folic acid.

Ferrous Fumarate: Gastrointestinal disturbances (anorexia, nausea, diarrhea, constipation) occur occasionally, but are usually mild and may subside with continuation of therapy. Although the absorption of iron is best when taken between meals, giving Integra Plus™ after meals may control occasional G.I. disturbances. Integra Plus™ 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 Plus™ should be stored beyond the reach of children to prevent against accidental iron poisoning. Keep this product and all drugs out of 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.

HOW SUPPLIED: Integra Plus™ are bright yellow (body) and maroon (cap) capsules imprinted "US" logo in maroon and "Integra Plus" in bright yellow. Child resistant bottles of 90 capsules NDC# 52747-712-60. Dispense in a tight, light-resistant container as defined in the USP/NF with a child resistant closure. Store at controlled room temperature 15° to 30°C (59° to 86° F). Keep in a cool, dry place. Capsules are not USP.

CAUTION: Rx only.

Made in the USA exclusively for U.S. Pharmaceutical Corporation, P.O. Box 360465, Decatur, GA 30036. All rights reserved. The appearance and the name of Integra Plus™ and the appearance of the ferrous fumarate/polysaccharide iron complex combination are registered trademarks of U.S. Pharmaceutical Corporation. Registered trademark has been applied for. The Integra Plus™ exclusive formula has been manufactured under one or several exclusive United States patents. In addition, the appearance, design and Integra Plus™ product literature and any statement therein, has been protected by U.S. and International Trademark Laws. Legal action will be taken against all violators. The use of the product information pamphlet is expressly prohibited without prior consent.

Rev. 10/2010