

IROSPAN 24/6- iron, folic acid, vitamin/mineral supplement
WOMENS CHOICE PHARMACEUTICALS LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Irospan 24/6

IROSPAN TABLET DESCRIPTION : Each light blue capsule-shaped film coated tablet has a pleasant sweet flavor with WC002 imprinted on one side.

SUCCINIC ACID TABLET DESCRIPTION: Each white round film coated tablet has a pleasant sweet flavor with WC imprinted on one side.

Clinical Pharmacology : Iron is an essential component in the formation of hemoglobin. Adequate amounts of iron are necessary for effective erthropoiesis. Iron also serves as a cofactor of several essential enzymes, including cytochromes that are involved in electron transport.

Folic acid is required for nucleoprotein synthesis and the maintenance of normal erthropoiesis. Folic acid is converted in the liver and plasma to its metabolically active form, tetrahydrofolic acid, by dihydrofolate reductase.

Vitamin B12 is required for the maintenance of normal erthropoiesis, nucleoprotein and myelin synthesis, cell reproduction and normal growth. Intrinsic factor, a glycoprotein secreted by the gastric mucosa, is required for active absorption of Vitamin B12 from the gastrointestinal tract.

INDICATION AND USAGE: IROSPAN 24/6 is indicated for the treatment of all anemias that are responsive to oral iron therapy. These include: hypochromic anemia associated with pregnancy, chronic and/or acute blood loss, metabolic disease, post-surgical convalescence, and dietary needs.

Warnings: Ingestion of more than 3 grams of omega-fatty acids per day has been shown to have potential antithrombotic effects, including increased bleeding time and INR. Administration of omega-3 fatty acids should be avoided in patients on anticoagulants and in those known to have an inherited or acquired bleeding diathesis.

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

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. KEEP THIS PRODUCT OUT OF THE REACH OF CHILDREN. In case of accidental overdose, call a doctor or poison control center immediately.

P recautions: Folic acid in doses above 0.1mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations remain progressive. This product contains formate, which if consumed above the recommended level, could cause visual impairment and other health effects. Do not take more than the recommended amount. If you are pregnant, nursing, or taking any medications consult your doctor before use. Discontinue use and consult your doctor if any adverse reactions occur. Not intended for use by persons under the age of 18.

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

Dosage and Administration

Usual adult dosage is 1 tablet daily or as directed by a physician. The IROSPAN® carton contains a 30 day course of iron therapy that consists of 24 light blue tablets and 6 white tablets. Take 1 light blue tablet daily for 24 days, followed by 1 white tablet daily for 6 days. After the 30 tablets have been taken, a new course may be started if prescribed.

How Supplied

IROSPAN® 24/6 tablets for oral administration are available in four child resistant blister cards containing 30 tablets (24 light blue tablets and 6 white tablets) (NDC 50967-126-30)

Irospan

24/6 TABLETS

Iron / Folic Acid / Supplement Tablets and Succinic Acid Tablets provide a 30 day oral iron supplement therapy

4 blister cards; 30 Tablets (24 light blue tablets & 6 white tablets) NDC 50967-126-30

CLINICAL PHARMACOLOGY: Iron is an essential component in the formation of hemoglobin. Adequate amounts of iron are necessary for effective erythropoiesis. Iron also serves as a cofactor of several essential enzymes, including cytochromes that are involved in electron transport.

Folic acid is required for nucleoprotein synthesis and the maintenance of normal erythropoiesis. Folic acid is converted in the liver and plasma to its metabolically active form, tetrahydrofolic acid, by dihydrofolate reductase.

Vitamin B12 is required for the maintenance of normal erythropoiesis, nucleoprotein and myelin synthesis, cell reproduction and normal growth. Intrinsic factor, a glycoprotein secreted by the gastric mucosa, is required for active absorption of Vitamin B12 from the gastrointestinal tract.

INDICATIONS AND USAGE: IROSPAN® 24/6 is indicated for the treatment of all anemias that are responsive to oral iron therapy. These include: hypochromic anemia associated with pregnancy, chronic and/or acute blood loss, metabolic disease, post-surgical convalescence, and dietary needs.

CONTRAINDICATIONS: This product is contraindicated in patients with a known hypersensitivity to any of the ingredients. Hemolytic anemia, hemochromatosis, and hemosiderosis are contraindications to iron therapy.

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

PRECAUTIONS: Folic acid in doses above 0.1mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations remain progressive. This product contains formate, which if consumed above the recommended level, could cause visual impairment and

other health effects. Do not take more than the recommended amount. If you are pregnant, nursing, or taking any medications consult your doctor before use. Discontinue use and consult your doctor if any adverse reactions occur. Not intended for use by persons under the age of 18.

ADVERSE REACTIONS: Adverse reactions with iron therapy may include constipation, diarrhea, nausea, vomiting, dark stools, and abdominal pain. Adverse reactions with iron therapy are usually transient. Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

DOSAGE AND ADMINISTRATION: Usual adult dosage is 1 tablet daily or as directed by a physician. The IROSPAN® 24/6 carton contains a 30 day course of iron therapy that consists of 24 light blue tablets and 6 white tablets. Take 1 light blue tablet daily for 24 days, followed by 1 white tablet daily for 6 days. After the 30 tablets have been taken, a new course may be started if prescribed.

HOW SUPPLIED: IROSPAN® 24/6 tablets for oral administration are available in four child resistant blister cards containing 30 tablets (24 light blue tablets and 6 white tablets) (NDC 50967-126-30)

Store at controlled room temperature 15°-30°(59°-86°F) RX only

Distributed by:
Women's Choice Pharmaceuticals • Gilbert, AZ 85233 • (877) 774-4949

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US Patent #6,526,542, #6,488,361, #6,169,016
IROSPAN® is a registered trademark of Women's Choice Pharmaceuticals, LLC

IRD-0111

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. KEEP THIS PRODUCT OUT OF THE REACH OF CHILDREN. In case of accidental overdose, call a doctor or poison control center immediately.

IROSPAN TABLET DESCRIPTION: Each light blue capsule-shaped film coated tablet has a pleasant sweet flavor with WC002 imprinted on one side.

Supplement Facts

Serving Size: 1 Tablet		
	Amount per Serving	% DV
Vitamin C (as Sodium Ascorbate)	100 mg	167%
Formical® (Calcium Formate)	155 mg	16%
B1 (Thiamine HCL)	5 mg	333%
B2 (Riboflavin)	5 mg	294%
B3 (Niacin)	25 mg	125%
B6 (Pyridoxine HCL)	30 mg	1500%
Folic Acid	1000 mcg	250%
B12 (Cyanocobalamin)	10 mcg	167%
B7 (Biotin)	300 mcg	100%
B5 (d-Calcium Panthothenate)	7 mg	70%
Iron (Ferrous bisGlycinate Chelate)	65 mg	361%
Iron (Polysaccharide Iron Complex)	65 mg	361%

*% Daily Value Based on a 2800 Calorie Diet

Other Ingredients: Microcrystalline Cellulose, Magnesium Stearate, Povidone, Polyvinyl Alcohol-Partially Hydrolyzed, PEG 3350, Titanium Dioxide, Talc, and FD&C Blue #1, Saccharin, Carnauba Wax.



SUCCINIC ACID TABLET DESCRIPTION: Each white round film coated tablet has a pleasant sweet flavor with WC imprinted on one side.

Supplement Facts

Serving Size: 1 Tablet		
	Amount per Serving	% DV
Vitamin C (as Sodium Ascorbate)	100 mg	167%
Calcium (Calcium Carbonate)	100 mg	10%
B1 (Thiamine HCL)	5 mg	333%
B2 (Riboflavin)	5 mg	294%
B3 (Niacin)	25 mg	125%
B6 (Pyridoxine HCL)	30 mg	1500%
Folic Acid	1000 mcg	250%
B12 (Cyanocobalamin)	10 mcg	167%
B7 (Biotin)	300 mcg	100%
B5 (d-Calcium Panthothenate)	7 mg	70%
Succinic Acid	150 mg	1

*% Daily Value Based on a 2800 Calorie Diet (DV not established)

Other Ingredients: Microcrystalline Cellulose, Magnesium Stearate, Povidone, Polyvinyl Alcohol-Partially Hydrolyzed, PEG 3350, Titanium Dioxide, Talc, Saccharin, Carnauba Wax.

Women's Choice
PHARMACEUTICALS

Gilbert, AZ 85233 • (877) 774-4949
www.wcpharma.com

IROSPAN 24/6

iron, folic acid, vitamin/mineral supplement kit

Product Information

Product Type HUMAN PRESCRIPTION DRUG **Item Code (Source)** NDC:50967-126

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50967-126-30	4 in 1 CARTON	04/15/2011	
1		1 in 1 BLISTER PACK		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1		24

Part 1 of 2

IROSPAN 24/6

iron, multi-vitamin mineral supplement tablet

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM ASCORBATE (UNII: S033EH8359) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	100 mg
CALCIUM FORMATE (UNII: NP3JD65NPY) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	155 mg
THIAMINE HYDROCHLORIDE (UNII: M572600E5P) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE HYDROCHLORIDE	5 mg
RIBOFLAVIN SODIUM (UNII: 04SRR95RP8) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN SODIUM	5 mg
NIACIN (UNII: 2679MF687A) (NIACIN - UNII:2679MF687A)	NIACIN	25 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	30 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	10 ug
BIOTIN (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)	BIOTIN	300 ug
CALCIUM PANTOTHENATE (UNII: 568ET80C3D) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	300 ug
FERROUS BISGLYCINATE (UNII: SFW1D987QV) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	65 mg
IRON DEXTRAN (UNII: 95HR524N2M) (FERRIC CATION - UNII:91O4LML611)	FERRIC CATION	65 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE (UNII: FZ989GH94E)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
SACCHARIN (UNII: FST467XS7D)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	

Product Characteristics

Color	blue	Score	no score
Shape	OVAL	Size	18mm
Flavor		Imprint Code	WC;002
Contains			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/15/2011	

Part 2 of 2

IROSPAN SUCCINIC ACID

succinic acid with multi-vitamin/mineral supplement tablet, film coated

Product Information

Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM ASCORBATE (UNII: S033EH8359) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	100 mg
CALCIUM CARBONATE (UNII: H0G9379FGK) (CARBONATE ION - UNII:7UJQ5OPE7D)	CALCIUM CARBONATE	100 mg
THIAMINE HYDROCHLORIDE (UNII: M572600E5P) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE HYDROCHLORIDE	5 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	5 mg
NIACIN (UNII: 2679MF687A) (NIACIN - UNII:2679MF687A)	NIACIN	25 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	30 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	10 ug
BIOTIN (UNII: 6S06U10H04) (BIOTIN - UNII:6S06U10H04)	BIOTIN	300 ug
CALCIUM PANTOTHENATE (UNII: 568ET80C3D) (PANTOTHENIC ACID - UNII:19F5HK2737)	PANTOTHENIC ACID	7 mg
SUCCINIC ACID (UNII: AB6MNQ6J6L) (SUCCINIC ACID - UNII:AB6MNQ6J6L)	SUCCINIC ACID	150 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE (UNII: FZ989GH94E)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	

POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	
SACCHARIN (UNII: FST467XS7D)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	WC;
Contains			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/15/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/15/2011	

Labeler - WOMENS CHOICE PHARMACEUTICALS LLC (833067841)

Registrant - WOMENS CHOICE PHARMACEUTICALS LLC (833067841)

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WOMENS CHOICE PHARMACEUTICALS LLC