

CENTRATEX- iron, sodium ascorbate, thiamine mononitrate, riboflavin, pyridoxine hydrochloride, folic acid, cyanocobalamin, niacinamide, calcium pantothenate, zinc sulfate, magnesium sulfate, manganese sulfate, and cupric sulfate anhydrous capsule
Centurion Labs, 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.

Centratex

Capsules

Capsules

Iron 106 mg, Sodium Ascorbate 200 mg, Thiamine 10 mg, Riboflavin 6 mg, Pyridoxine 5 mg, Folic Acid 1 mg, Cyanocobalamin 15 mcg, Niacinamide 30 mg, Pantothenic Acid 10 mg, Zinc 18.2 mg, Magnesium 6.9 mg

Copper (Copper sulfate)	0.8 mg
Manganese (Manganese Sulfate)	1.3 mg

A medical food, for use only under the direction and supervision of a licensed physician.

RX only

DESCRIPTION

Active Ingredients (Each capsule)

Ferrous Fumerate	106 mg(iron)
Vitamin C (Sodium Ascorbate)	200 mg
Vitamin B1 (Thiamine Mononitrate)	10 mg
Vitamin B2 (Riboflavin)	6 mg
Vitamin B6 (Pyridoxine HCL)	5 mg
Folic Acid	1 mg
Vitamin B12	15 mcg
Niacinamide	30 mg
Pantothenic Acid	10 mg
Zinc (Zinc Sulfate)	18.2 mg
Magnesium (Magnesium Sulfate)	6.9 mg

Copper (Copper Sulfate)	0.8 mg
Manganese (Manganese Sulfate)	1.3 mg

Inactive Ingredients

Microcrystalline Cellulose, Silica, Magnesium Stearate, Gelatin Capsule

INDICATIONS

For the treatment of anemia due to lack of iron and low folate as in menorrhagia, pregnancy, puberty, excessive blood loss, and advanced age. Also for treatment of conditions where iron and vitamin C deficiency occur together, along with a poor intake or increased need for B-complex vitamins in chronic and acute illness, as well as cases of metabolic stress, and in periods of extended recovery.

CONTRAINDICATIONS

Centratex is contraindicated in patients with a known hypersensitivity to any of its ingredients. Iron compounds are contraindicated in patients with hemosiderosis, hemochromatosis, and hemolytic anemias. Folic acid may obscure signs and symptoms of pernicious anemia and is therefore a contraindication as well.

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. Iron is toxic and has been shown to cause severe reactions in children including death.

Warning

Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B-12 is deficient.

PRECAUTIONS

General

Folic acid in doses above 0.1 mg – 0.4 mg daily may obscure pernicious anemia, in that hematologic remission can occur while neurological manifestations remain progressive.

PEDIATRIC USE

Safety and effectiveness in pediatric patients has not been established.

GERIATRIC USE

No clinical studies have been performed in patients over 65 to determine whether older persons respond differently from younger persons. Physicians should consider that

elderly persons may have decreased hepatic, renal, or cardiac function.

ADVERSE REACTION

Allergic sensitizations have been reported following both oral and parenteral administration of folic acid. Gastrointestinal disturbances (anorexia, nausea, diarrhea, constipation) occur occasionally, but are usually mild and subside with continuation of therapy and physician encouragement. Although the absorption of iron is best when taken between meals, occasional G.I. disturbances may be controlled by giving Centrutex shortly after meals.

DOSAGE AND ADMINISTRATION

Adults only: 1 capsule daily between meals, orally. Not recommended in children.

HOW SUPPLIED

Centrutex is supplied as a natural gelatin capsule with tan speckled powder. Centrutex is available in bottles of 100 (NDC 23359-100-10) and bottles of 30 (NDC 23359-100-30) 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 degrees C (59-86 degrees F) Keep in a cool, dry place.

RX ONLY

Centurion Labs, LLC
Birmingham, AL 35243

Rev. 8/17

PRINCIPAL DISPLAY PANEL - 30 Capsule Bottle Label

NDC 23359-100-30

Centrutex

Iron (Ferrous Fumarate, anhydrous)	106 mg
Vitamin C (Sodium Ascorbate)	200 mg
Vitamin B1 (Thiamine Mononitrate)	10 mg
Vitamin B2 (Riboflavin)	6 mg
Vitamin B6 (Pyridoxine HCl)	5 mg
Vitamin B12 (Cyanocobalamin Concentrate)	15 mcg
Folic Acid	1 mg
Niacinamide (Nicotinamide)	30 mg
Pantothenic Acid (Calcium Pantothenate)	10 mg
Zinc (Zinc Sulfate)	18.2 mg
Magnesium (Magnesium Sulfate)	6.9 mg

Manganese (Manganese Sulfate)
Copper (Cupric Sulfate)

1.3 mg
0.8 mg

CENTURION LABS Rx Only

Net Contents: 30 capsules

NDC 23359-100-30

Centratex

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

Dosage and Administration: Adults only: 1 capsule daily, between meals, orally. Do not exceed recommended dosage. Do not administer to children.

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

In case of accidental overdose call a doctor or poison control center immediately. Iron is toxic. When overdoses are ingested by children, severe reactions, including fatalities, have resulted. Centratex should be stored beyond the reach of children to protect against accidental iron poisoning. Keep this and all drugs out of the reach of children.

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

See package insert for full prescribing information.

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

Dispense in a tight, light-resistant container with a child-resistant closure as defined in USP&N.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured For:
Centurion Labs, LLC • Birmingham, AL 35243

3 23359 10030 7 Rev. 03/11

Iron (Ferrous Fumarate, anhydrous)	106 mg
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Zinc (Zinc Sulfate)	18.2 mg
Magnesium (Magnesium Sulfate)	6.9 mg
Manganese (Manganese Sulfate)	1.3 mg
Copper (Cupric Sulfate)	0.8 mg

CENTURION LABS Rx Only

Net Contents: 30 capsules

PRINCIPAL DISPLAY PANEL - 100 Capsule Bottle Label

NDC 23359-100-10

Centratex

Iron (Ferrous Fumarate, anhydrous)	106 mg
Vitamin C (Sodium Ascorbate)	200 mg
Vitamin B1 (Thiamine Mononitrate)	10 mg
Vitamin B2 (Riboflavin)	6 mg
Vitamin B6 (Pyridoxine HCl)	5 mg
Vitamin B12 (Cyanocobalamin Concentrate)	15 mcg
Folic Acid	1 mg
Niacinamide (Nicotinamide)	30 mg
Pantothenic Acid (Calcium Pantothenate)	10 mg
Zinc (Zinc Sulfate)	18.2 mg
Magnesium (Magnesium Sulfate)	6.9 mg
Manganese (Manganese Sulfate)	1.3 mg
Copper (Copper Sulfate)	0.8 mg

CENTURION LABS

Rx Only

Net Contents: 100 capsules

NDC 23359-100-10

Centratex

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

Dosage and Administration: Adults only: 1 capsule daily, between meals, orally. Do not exceed recommended dosage. Do not administer to children.

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

In case of accidental overdose call a doctor or poison control center immediately. Iron is toxic. When overdoses are ingested by children, severe reactions, including fatalities, have resulted. Centratex should be stored beyond the reach of children to protect against accidental iron poisoning. Keep this and all drugs out of the reach of children.

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CENTURION LABS Rx Only
Net Contents: 100 capsules

Precautions: General: Folic acid in doses above 0.1 mg - 0.4 mg daily may obscure pernicious anemia. In that hematologic remission can occur with neurological manifestations remain progressive.

See package insert for full prescribing information.

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Dispense in a tight, light-resistant container with a child-resistant closure as defined in USP/NE.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured For:
Centurion Labs, LLC. • Birmingham, AL 35243



Rev. 03/11

CENTRATEx

iron, sodium ascorbate, thiamine mononitrate, riboflavin, pyridoxine hydrochloride, folic acid, cyanocobalamin, niacinamide, calcium pantothenate, zinc sulfate, magnesium sulfate, manganese sulfate, and cupric sulfate anhydrous capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:23359-100
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IRON (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7)	IRON	106 mg
SODIUM ASCORBATE (UNII: S033EH8359) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	200 mg
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	10 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	6 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	5 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	15 ug
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	30 mg
CALCIUM PANTOTHENATE (UNII: 568ET80C3D) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	10 mg
ZINC SULFATE (UNII: 89DS0H96TB) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	18.2 mg
MAGNESIUM SULFATE, UNSPECIFIED (UNII: DE08037SAB) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM SULFATE, UNSPECIFIED	6.9 mg
MANGANESE SULFATE (UNII: W00LYS4T26) (MANGANESE CATION (2+) - UNII:H6EP7W5457)	MANGANESE CATION (2+)	1.3 mg
CUPRIC SULFATE ANHYDROUS (UNII: KUW2Q3U1V) (CUPRIC CATION - UNII:8CBV67279L)	CUPRIC CATION	0.8 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
GELATIN (UNII: 2G86QN327L)	

Product Characteristics

Color	brown (clear with tan speckled powder)	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:23359-100-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2009	
2	NDC:23359-100-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/14/2009	

Labeler - Centurion Labs, LLC (016481957)

Revised: 1/2024

Centurion Labs, LLC