

**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](#).*

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**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

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

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

**RX only**

**DESCRIPTION**

**Active Ingredients (Each capsule)**

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|                                   |                 |
|-----------------------------------|-----------------|
| Ferrous Fumerate                  | 106<br>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          |

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**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 Centratex shortly after meals.

## **DOSAGE AND ADMINISTRATION**

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

## **HOW SUPPLIED**

Centratex is supplied as a natural gelatin capsule with tan speckled powder. Centratex 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

**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 (Cupric Sulfate)                  | 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.

|  |         |
|--|---------|
| Iron (Ferrous Fumarate, anhydrous)       | 106 mg  |
| Vitamin C (Sodium Ascorbate)             | 200 mg  |
| Vitamin B1 (Thiamine Mononitrate)        | 10 mg   |
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**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/NF.

**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

**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.

|  |         |
|--|---------|
| Iron (Ferrous Fumarate, anhydrous)       | 106 mg  |
| Vitamin C (Sodium Ascorbate)             | 200 mg  |
| Vitamin B1 (Thiamine Mononitrate)        | 10 mg   |
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| Vitamin B12 (Cyanocobalamin Concentrate) | 15 mcg  |
| Folic Acid                               | 1 mg    |
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| Zinc (Zinc Sulfate)                      | 18.2 mg |
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| Copper (Cupric Sulfate)                  | 0.8 mg  |

**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/NF.

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

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



3 23359 10010 9

**Rev. 03/11**

**CENTURION LABS Rx Only**

**Net Contents: 100 capsules**

**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**

|                                |                         |                           |               |
|--------------------------------|-------------------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN PRESCRIPTION DRUG | <b>Item Code (Source)</b> | NDC:23359-100 |
| <b>Route of Administration</b> | ORAL                    |                           |               |

**Active Ingredient/Active Moiety**

| Ingredient Name   | Basis of Strength              | Strength |
|---|--------------------------------|----------|
| <b>IRON</b> (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7)                                       | IRON                           | 106 mg   |
| <b>Sodium Ascorbate</b> (UNII: S033EH8359) (ASCORBIC ACID - UNII:PQ6CK8PD0R)                  | ASCORBIC ACID                  | 200 mg   |
| <b>THIAMINE MONONITRATE</b> (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)               | THIAMINE                       | 10 mg    |
| <b>Riboflavin</b> (UNII: TLM2976OFR) (Riboflavin - UNII:TLM2976OFR)                           | Riboflavin                     | 6 mg     |
| <b>Pyridoxine Hydrochloride</b> (UNII: 68Y4CF58BV) (Pyridoxine - UNII:KV2JZ1BI6Z)             | Pyridoxine Hydrochloride       | 5 mg     |
| <b>Folic Acid</b> (UNII: 935E97BOY8) (Folic Acid - UNII:935E97BOY8)                           | Folic Acid                     | 1 mg     |
| <b>Cyanocobalamin</b> (UNII: P6YC3EG204) (Cyanocobalamin - UNII:P6YC3EG204)                   | Cyanocobalamin                 | 15 ug    |
| <b>Niacinamide</b> (UNII: 25X5I18RD4) (Niacinamide - UNII:25X5I18RD4)                         | Niacinamide                    | 30 mg    |
| <b>Calcium Pantothenate</b> (UNII: 568ET80C3D) (CALCIUM CATION - UNII:2M83C4R6ZB)             | CALCIUM CATION                 | 10 mg    |
| <b>Zinc Sulfate</b> (UNII: 89DS0H96TB) (ZINC CATION - UNII:13S1S8SF37)                        | ZINC CATION                    | 18.2 mg  |
| <b>MAGNESIUM SULFATE, UNSPECIFIED</b> (UNII: DE08037SAB) (MAGNESIUM CATION - UNII:T6V3LHY838) | MAGNESIUM SULFATE, UNSPECIFIED | 6.9 mg   |
| <b>Manganese Sulfate</b> (UNII: W00LYS4T26) (MANGANESE CATION (2+) - UNII:H6EP7W5457)         | MANGANESE CATION (2+)          | 1.3 mg   |
| <b>Cupric Sulfate Anhydrous</b> (UNII: KUW2Q3U1VV) (CUPRIC CATION - UNII:8CBV67279L)          | CUPRIC CATION                  | 0.8 mg   |

**Inactive Ingredients**

| Ingredient Name                                       | Strength |
|---|----------|
| <b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U) |          |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)             |          |
| <b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)          |          |
| <b>GELATIN</b> (UNII: 2G86QN327L)                     |          |

**Product Characteristics**

|                 |  |                     |          |
|-----------------|--|---------------------|----------|
| <b>Color</b>    | BROWN (clear with tan speckled powder) | <b>Score</b>        | no score |
| <b>Shape</b>    | CAPSULE                                | <b>Size</b>         | 19mm     |
| <b>Flavor</b>   |  | <b>Imprint Code</b> |          |
| <b>Contains</b> |  |                     |          |

**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)

**Registrant** - Centurion Labs, LLC (016481957)

**Establishment**

| Name                                | Address | ID/FEI    | Business Operations    |
|-------------------------------------|---------|-----------|------------------------|
| Contract Pharmaceutical Corporation |         | 057795122 | manufacture(23359-100) |

Revised: 9/2019

Centurion Labs, LLC