

**PRENAISSANCE- calcium citrate, iron pentacarbonyl, cholecalciferol, .alpha.-tocopherol acetate, dl-, pyridoxine hydrochloride, folic acid, docusate sodium and doconexent capsule, liquid filled  
Acella 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.*

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**Prenaissance Capsules**

**Rx Only**

**DESCRIPTION:**

Prenaissance Capsules are a prescription prenatal/postnatal multivitamin/multimineral softgel capsule with DHA. Each softgel is brown in color, opaque and imprinted with "341" on one side.

**EACH SOFTGEL CONTAINS:**

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|                                     |         |
|-------------------------------------|---------|
| Vitamin C (ascorbic acid, USP)      | 28 mg   |
| Calcium (tricalcium phosphate, NF)  | 160 mg  |
| Iron (ferrous fumarate, USP)        | 29 mg   |
| Vitamin D3 (cholecalciferol, USP)   | 800 IU  |
| Vitamin E (d-alpha tocopherol, USP) | 30 IU   |
| Vitamin B6 (pyridoxine HCl, USP)    | 25 mg   |
| Folic Acid, USP                     | 1.25 mg |
| DHA (docosahexaenoic acid)          | 325 mg  |
| Docusate Sodium, USP                | 55 mg   |

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**OTHER INGREDIENTS:**

gelatin, glycerin, purified water, soybean oil, lecithin, yellow bees wax, natural creamy orange flavor, titanium dioxide, FD&C red #40, ethyl vanillin, FD&C yellow #5, FD&C blue #1.

**INDICATIONS:**

Prenaissance Capsules are a multivitamin/multimineral nutritional supplement with DHA indicated for use in the dietary management of patients with nutritional deficiencies or are in need of nutritional supplementation.

**CONTRAINDICATIONS:**

This product is contraindicated in patients with a known hypersensitivity to any of the ingredients. Do not take this product if you are presently taking mineral oil, unless

directed by a physician.

**WARNING:**

Ingestion of more than 3 grams of omega-3 fatty acids (such as DHA) per day has been shown to have potential antithrombotic effects, including an increased bleeding time and International Normalized Ratio (INR). Administration of omega-3 fatty acids should be avoided in patients taking anticoagulants and in those known to have an inherited or acquired predisposition to bleeding.

**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.

**PRECAUTIONS:**

Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B<sub>12</sub> is deficient. Folic acid in doses above 1.0 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations progress.

**ADVERSE REACTIONS:**

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

**CAUTION:**

Exercise caution to ensure that the prescribed dosage of DHA does not exceed 1 gram (1000 mg) daily.

**DOSAGE AND ADMINISTRATION:**

Usual adult dose is 1 (one) softgel daily or as directed by a physician.

**HOW SUPPLIED:**

Prenaissance Capsules are supplied in child-resistant bottles of 30 softgels (NDC# 42192-341-30).

Store at 20° - 25°C (68° - 77°F) [See USP].

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

All prescription substitutions and/or recommendations using this product shall be made subject to state and federal statutes as applicable. **Please note: this is not an Orange Book product and has not been subjected to FDA therapeutic equivalency or other equivalency testing. No representation is made as to**

**generic status or bioequivalency.** Each person recommending a prescription substitution using this product shall make such recommendations based on each such person's professional opinion and knowledge, upon evaluating the active ingredients, excipients, inactive ingredients and chemical information provided herein.

**MANUFACTURED FOR:**

Acella Pharmaceuticals, LLC  
 Alpharetta, GA 30009  
 1-800-541-4802

Rev. 0411

**PRINCIPAL DISPLAY PANEL - 30 Softgels**

NDC 42192-341-30

**Prenaissance Capsules**

R<sub>x</sub> Prenatal Vitamin and DHA

R<sub>x</sub> only                    30 Softgels

**Acella**  
 PHARMACEUTICALS, LLC

**PRENAISSANCE**

calcium citrate, iron pentacarbonyl, cholecalciferol, .alpha.-tocopherol acetate, dl-, pyridoxine hydrochloride, folic acid, docusate sodium and doconexent capsule, liquid filled

**Product Information**

|                                |                         |                           |               |
|--------------------------------|-------------------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN PRESCRIPTION DRUG | <b>Item Code (Source)</b> | NDC:42192-341 |
| <b>Route of Administration</b> | ORAL                    |                           |               |

**Active Ingredient/Active Moiety**

| Ingredient Name | Basis of Strength | Strength |
|-----------------|-------------------|----------|
|-----------------|-------------------|----------|

|   |                        |          |
|---|------------------------|----------|
| <b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)                   | ASCORBIC ACID          | 28 mg    |
| <b>TRICALCIUM PHOSPHATE</b> (UNII: K4C08XP666) (CALCIUM CATION - UNII:2M83C4R6ZB)           | CALCIUM CATION         | 160 mg   |
| <b>FERROUS FUMARATE</b> (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR)               | FERROUS CATION         | 29 mg    |
| <b>CHOLECALCIFEROL</b> (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)               | CHOLECALCIFEROL        | 800 [iU] |
| <b>.ALPHA.-TOCOPHEROL, D-</b> (UNII: N9PR3490H9) (.ALPHA.-TOCOPHEROL, D- - UNII:N9PR3490H9) | .ALPHA.-TOCOPHEROL, D- | 30 [iU]  |
| <b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)           | PYRIDOXINE             | 25 mg    |
| <b>FOLIC ACID</b> (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)                         | FOLIC ACID             | 1.25 mg  |
| <b>DOCONEXENT</b> (UNII: ZAD9OKH9JC) (DOCONEXENT - UNII:ZAD9OKH9JC)                         | DOCONEXENT             | 325 mg   |
| <b>DOCUSATE SODIUM</b> (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)                      | DOCUSATE SODIUM        | 55 mg    |

## Inactive Ingredients

| Ingredient Name                                 | Strength |
|---|----------|
| <b>GELATIN</b> (UNII: 2G86QN327L)               |          |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)              |          |
| <b>WATER</b> (UNII: 059QF0KO0R)                 |          |
| <b>SOYBEAN OIL</b> (UNII: 241ATL177A)           |          |
| <b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)            |          |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)      |          |
| <b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)   |          |
| <b>ETHYL VANILLIN</b> (UNII: YC9ST449YJ)        |          |
| <b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M) |          |
| <b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)   |          |

## Product Characteristics

|                 |         |                     |          |
|-----------------|---------|---------------------|----------|
| <b>Color</b>    | BROWN   | <b>Score</b>        | no score |
| <b>Shape</b>    | CAPSULE | <b>Size</b>         | 25mm     |
| <b>Flavor</b>   |         | <b>Imprint Code</b> | 341      |
| <b>Contains</b> |         |                     |          |

## Packaging

| # | Item Code        | Package Description                                | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:42192-341-30 | 30 in 1 CAPSULE; Type 0: Not a Combination Product | 06/13/2011           |                    |

## Marketing Information

| Marketing Category       | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------------|--|----------------------|--------------------|
| UNAPPROVED DRUG<br>OTHER |  | 06/13/2011           |                    |

**Labeler** - Acella Pharmaceuticals, LLC (825380939)

**Registrant** - Acella Pharmaceuticals, LLC (825380939)

## Establishment

| Name                        | Address | ID/FEI    | Business Operations    |
|-----------------------------|---------|-----------|------------------------|
| Acella Pharmaceuticals, LLC |         | 825380939 | manufacture(42192-341) |

Revised: 1/2024

Acella Pharmaceuticals, LLC