PRENAISSANCE PLUS- 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.

Prenaissance Plus

Rx Only

DESCRIPTION:

Prenaissance Plus is a prescription prenatal/postnatal multivitamin/multimineral softgel capsule with DHA. Each softgel is purple in color, opaque and imprinted with "343" on one side.

EACH SOFTGEL CONTAINS:

Calcium (Calcium citrate)	100 mg
Iron (Carbonyl Iron)	28 mg
Vitamin D3 (Cholecalciferol)	400 IU
Vitamin E (dl-alpha tocopherol acetate	30 IU
Vitamin B6 (Pyridoxine HCl)	25 mg
Folic Acid	1 mg
Docusate Sodium	50 mg
DHA (Docosahexaenoic acid)	250 mg

OTHER INGREDIENTS:

soybean oil, yellow bee's wax, lecithin, natural orange cream flavoring, gelatin, glycerine, purified water, carmine, titanium dioxide, ethyl vanillin, FD&C#40, and FD&C Blue #1.

INDICATIONS:

Prenaissance Plus is a multivitamin/mineral prescription drug indicated for use in improving the nutritional status of women prior to conception, throughout pregnancy, and in the postnatal period for both lactating and nonlactating mothers.

CONTRAINDICATIONS:

This product is contraindicated in patients with a known hypersensitivity to any of the ingredients.

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_{12} 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.

NOTICE:

Contact the moisture can discolor or erode the capsule.

HOW SUPPLIED:

Prenaissance Plus is supplied in child-resistant bottles of 30 softgels (NDC# 42192-343-30).

Store at 15° - 30°C (59° - 86°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

PRINCIPAL DISPLAY PANEL - 30 Softgels

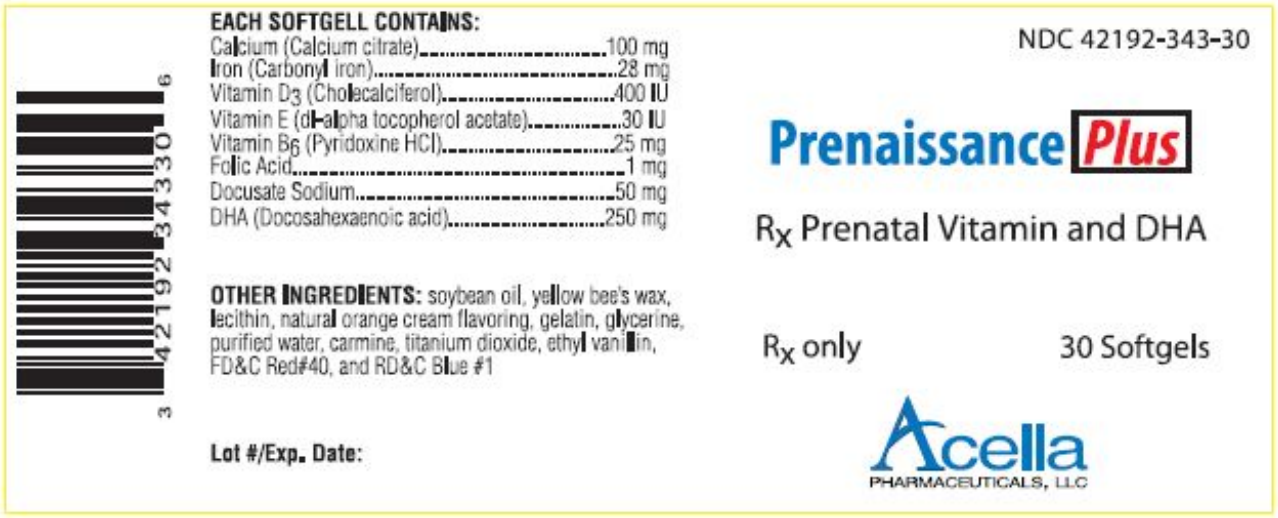
NDC 42192-343-30

Prenaissance *Plus*

R_x Prenatal Vitamin and DHA

R_x only 30 Softgels

Acella
PHARMACEUTICALS, LLC



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Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42192-343
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

CALCIUM CITRATE (UNII: MLM29U2X85) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CITRATE ANHYDROUS	100 mg
IRON PENTACARBONYL (UNII: 6WQ62TAQ6Z) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	28 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	400 [iU]
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	30 [iU]
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	25 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg
DOCONEXENT (UNII: ZAD9OKH9JC) (DOCONEXENT - UNII:ZAD9OKH9JC)	DOCONEXENT	250 mg

Inactive Ingredients

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

Product Characteristics

Color	PURPLE	**Score**	no score
Shape	CAPSULE	**Size**	25mm
Flavor		**Imprint Code**	343
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42192-343-30	30 in 1 CAPSULE; Type 0: Not a Combination Product	10/07/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		10/07/2011	

Labeler - Acella Pharmaceuticals, LLC (825380939)

Registrant - Acella Pharmaceuticals, LLC (825380939)

Establishment

Name	Address	ID/FEI	Business Operations
Acella Pharmaceuticals, LLC		825380939	manufacture(42192-343)