

VITALARA- beta carotene, ascorbic acid, cholecalciferol, dl-alpha-tocopheryl acetate, pyridoxine hydrochloride, folic acid, 5-methyl tetrahydrofolate, calcium salt, cyanocobalamin, biotin, calcium carbonate, ferrous bisglycinate, potassium iodine, magnesium oxide tablet
Aletris Pharmaceuticals, LLC

VITALARA
PRENATAL/POSTNATAL
Dietary Supplement

VITALARA-Dispensed by Prescription

VITALARA- beta carotene, ascorbic acid, cholecalciferol, dl-alpha-tocopheryl acetate, pyridoxine hydrochloride, folic acid, 5-methyl tetrahydrofolate, calcium salt, cyanocobalamin, biotin, calcium carbonate, ferrous bisglycinate, potassium iodine, and magnesium oxide tablet.

Serving Size: 1 Tablet		
Servings Per Container: 30		
Each Tablet Contains:		%DV
Vitamin A (as Beta-Carotene)	300 mcg RAE	23%
Vitamin C (as ascorbic acid)	60 mg	50%
Vitamin D3 (as cholecalciferol)	10 mcg	67%
Vitamin E (as dl-Alpha-Tocopheryl Acetate)	45 mg	24%
Vitamin B6 (as pyridoxine HCl)	26 mg	1300%
Folate (From Folic Acid) (From 5-Methyl Tetrahydrofolate, Calcium Salt)	1670 mcg DFE	278%
Vitamin B12 (as Cyanocobalamine)	13 mcg	464%
Biotin	28 mg	80%
Calcium (from Calcium Carbonate)	80 mg	6%
Ferrochel™ Iron (as ferrous BisGlycinate Chelate)	12 mg	44%
Iodine (as potassium iodide)	150 mcg	52%
Magnesium (as Magnesium oxide)	25 mg	6%
* -Percent Daily Value for pregnant and/or lactating women		

OTHER INGREDIENTS: Modified Cellulose, Stearic Acid, Croscarmellose Sodium, Silicon Dioxide, Magnesium Stearate, Polyethylene Glycol, Polydextrose, Titanium Dioxide, FD&C #1 Blue Lake

Allergen: NONE

DESCRIPTION

VITALARA is a prescription prenatal/postnatal multivitamin/ multimineral dietary supplement.

INDICATIONS

VITALARA is a multivitamin/multimineral dietary supplement indicated for the use in improving the nutritional status of women throughout pregnancy and in the postnatal period for both lactating and non-lactating mothers.

CONTRADINDICATIONS

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

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 the case of accidental overdose, call a doctor or poison control center immediately.

ADVERSE REACTIONS

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

You should call your doctor for medical advice about serious adverse events. To report adverse side effects or to obtain product information, contact: Aletris Pharmaceuticals, LLC at 228-207-8112.

DOSAGE AND ADMINISTRATION

Before, during and/or after pregnancy, one tablet daily with food or as directed by a physician.

PRECAUTION:

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

STORAGE

Store at 20°-25°C (68°-77°F) excursions permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature.] Avoid excessive heat, light and moisture.

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60010-890-74

VITALARA

PRENATAL/POSTNATAL
Dietary Supplement

30 TABLETS

Dispensed by Prescription

Peel back label at the bottom corner for full prescribing information.



Distributed by:
Aletris Pharmaceuticals, LLC
Biloxi, MS 39532
(228)207-8112



Peel Here

Middle Layer

**VITALARA- Dispensed by Prescription
Prenatal/Postnatal Dietary Supplement**

VITALARA- beta carotene, ascorbic acid, cholecalciferol, di-alpha-tocopheryl acetate, pyridoxine hydrochloride, folic acid, 5-methyl tetrahydrofolate, calcium salt, cyanocobalamin, biotin, calcium carbonate, ferrous bisglycinate, potassium iodine, and magnesium oxide tablet.

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ADVERSE REACTIONS

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DOSAGE AND ADMINISTRATION
Before, during and/or after pregnancy, one tablet daily with food or as directed by a physician.

HOW SUPPLIED

Bottles of 30 tablets (60010-890-74*). Tablet is blue, oblong.

60010-890-74



This product is a prescription-folate with or without other dietary ingredients that – due to increased folate levels increased risk associated with masking B12 deficiency (pernicious anemia) requires administration under the care of a licensed medical practitioner (64 FR 8760). 1-3 The most appropriate way to ensure pedigree reporting consistent with these regulatory guidelines and safety monitoring is to dispense this product only by prescription. This is not an Orange Book product. This product may be administered only under a physician's supervision and all prescriptions using this product shall be pursuant to state statutes as applicable. The ingredients, indication or claims of this product

Base Layer

**VITALARA- Dispensed by Prescription
Prenatal/Postnatal Dietary Supplement**

VITALARA- beta carotene, ascorbic acid, cholecalciferol, di-alpha-tocopheryl acetate, pyridoxine hydrochloride, folic acid, 5-methyl tetrahydrofolate, calcium salt, cyanocobalamin, biotin, calcium carbonate, ferrous bisglycinate, potassium iodine, and magnesium oxide tablet.

to be construed to be drug claims.

1. Federal Register Notice of August 2, 1973 (38 FR 20750)
2. Federal Register Notice of October 17, 1980 (45 FR 69043, 69044)
3. Federal Register Notice of March 5, 1996 (61 FR 8760)

1 Aletris Pharmaceuticals does not represent this product code to be National Drug Code (NDC). Product codes are formatted according to standard industry practice, to meet the formatting requirement by pedigree reporting and supply-chain control including pharmacies.

STORAGE AND HANDLING

STORAGE
Store at 20°-25° C (68°-77°F) excursions permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature.] Avoid excessive heat, light and moisture.

TAMPER EVIDENT

Double safety sealed for your protection. Do not use if either seal is broken or missing.

MADE IN USA

Ferrochel® is a register trademark of Balchem Corporation or its subsidiaries.

Distributed by:
Aletris Pharmaceuticals, LLC
Biloxi, MS 39532
(228)207-8112

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

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



60010-890-74 Rev. 0 10/2024

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Vitamin B6 (as Pyridoxine HCl)	26 mg	1300%
Folate (From Folic Acid)	1670 mcg DFE	278%
(From 5-Methyl Tetrahydrofolate, Calcium Salt)		
Vitamin B12 (as Cyanocobalamin)	13 mcg	464%
Biotin	28 mcg	60%
Calcium (from Calcium Carbonate)	60 mg	6%
Ferrochel™ Iron (as Ferrous BisGlycinate Chelate)	20mg	74%
Iodine (as Potassium Iodine)	150 mcg	52%
Magnesium (as Magnesium Oxide)	25 mg	6%

* Percent Daily Value for pregnant and/or lactating women

OTHER INGREDIENTS: Modified Cellulose, Stearic Acid, Croscarmellose Sodium, Silicon Dioxide, Magnesium Stearate, Polydextrose, Polyethylene Glycol, Titanium Dioxide, FD&C #1 Blue Lake
Allergen: NONE

VITALARA

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Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	86001089074
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	60 mg
BETA CAROTENE (UNII: 01YAE03M7J) (BETA CAROTENE - UNII:01YAE03M7J)	BETA CAROTENE	300 ug
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	10 ug
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	45 mg
PYRIDOXINE HCL (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	26 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1670 ug
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	13 ug
BIOTIN (UNII: 6S06U10H04) (BIOTIN - UNII:6S06U10H04)	BIOTIN	28 ug
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	80 mg
FERROUS BISGLYCINATE (UNII: SFW1D987QV) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	20 mg
POTASSIUM IODIDE (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	IODIDE ION	150 ug
MAGNESIUM OXIDE (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM CATION	25 mg

Inactive Ingredients

Ingredient Name	Strength
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	86001089074	30 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
dietary supplement		12/06/2024	

Supplement Facts	
Serving Size :	Serving per Container :
Amount Per Serving	% Daily Value
color	
shape	
scoring	1
size (solid drugs)	19 mm

Labeler - Aletris Pharmaceuticals, LLC (118956541)

Establishment			
Name	Address	ID/FEI	Business Operations
Aletris Pharmaceuticals, LLC		118956541	

Revised: 12/2024

Aletris Pharmaceuticals, LLC