ALTRIXA- vitamin tablet, coated Allegis Pharmaceuticals, LLC

Altrix Tablets

Suplement Facts

Supplement Facts Serving Size: 1 Tablet Servings per container: 30			
Amount Per Serving:	%	Daily Value	
Vitamin B12 (as cyanocobalamin)	4.5 mcg	188%	
Vitamin E	10 mg	67%	
Vitamin D3 (as Cholecalciferol)	20 mcg	100%	
Vitamin C (as Ascorbic Acid)	75 mg	100%	
Vitamin B6 (as Pyridoxine HCI)	2.5 mg	125%	
Thiamin (asThiamin Mononitrate)	1.4 mg	100%	
Riboflavin	1.6 mg	100%	
Niacin (as Niacinamide)	16.3 mg	104%	
Folate (from 1,000 mcg folic acid)	1667 mcg DFE	417%	
*Daily Values (DV) not established.			

Other Ingredients:

cellulose, vegetable stearic acid, silica, croscarmellose sodium, vegetable megnesium stearate, cellulose coating, titanium oxide.

Description

Altrixa Tablets is a prescription dietary supplement intended for oral administration.

Altrixa Tablets is to provide significant amounts of Vitamins B6, B12, C, D3, E, riboflavin, niacinamide, thiamine monoitrate, and folate to supplement the diet, and to help assure that nutritional deficiencies of these vitamines will not develop.

Contraindications

Altrixa Tablets are contraindicated in patients with a known hypersensitivity to any the contained ingredients. Do not take this produc if you are presently taking mineral oil,

unless directed by a licensed medical practitioner.

Precautions

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 0.1 mg daily may obsure pernicious anemia in that hematologic remission can occur while neurological manifestations progress. Altrxia tablets should only be used under the direction and supervision of a licensed medical practitioner.

Warnings

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

In case of accidental overdose, call a licensed medical practitioner or poison control center immediately.

For use under the supervision of a licensed medical practitioner.

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

Adverse Reactions

Allergic sensitization has been reported following both oral and parenteral administration of folic acid. You may report side effects by calling Allegis Pharmaceuticals at 1-866-633-9033 or the FDA by calling 1-800-FDA-1088

Doseage and Administration

Usual adult dose is one tablet daily, or as prescribed by a licensed medical practitioner.

How Supplied

Altrix Tablets are avaialble as white, round tablets with AL07 imprint and are available in 30 count bottles (28595-715-30).

Manufactred in the USA for:

Allegis pharmaceuticals, LLC.

Canton MS 39046

Rev. 01/2024

Storage

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F). [See USP Controlled Room Temperature.] Protect from light and moisture.Tamper Evident: Do not use if seal if broken or missing.

Statements

These statements have not been evaluated by the FDA. This product is not intended to

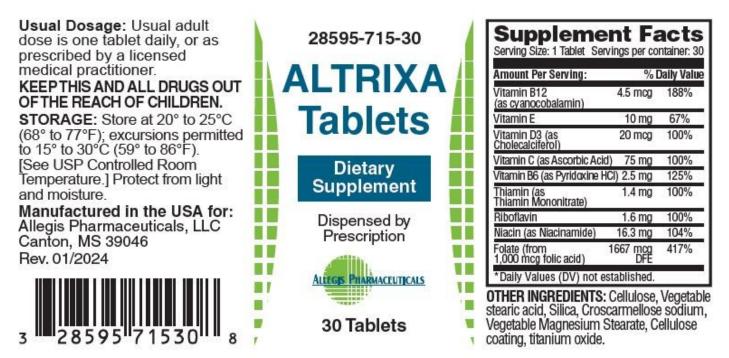
diagnose, treat, cure, or prevent any disease.

† This product is a prescription-folate with or without other dietary ingredients that – due to increased folate levels increased risk associated with masking of B12 deficiency (pernicious anemia) requires administration under the care of a licensed medical practitioner (61 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 are not to be construed to be drug claims.

1. Federal Register Notice of August 2, 1973 (38 FR20750) 2. Federal Register Notice of October 17, 1980 (45 FR69043, 69044) 3. Federal Register Notice of March 5, 1996 (61 FR 8760)

Label



ALTRIXA					
vitamin tablet, coated					
Product Information					
Product Type	DIETARY SUPPLEMENT	ltem Code	(Source)	NHRIC:285	595-715
Route of Administration	ORAL				
	Malata				
Active Ingredient/Active	мојету				
Ingred	ient Name		Basis of Str	ength	Strength

CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	4.5 ug
.ALPHATOCOPHEROL CALCIUM SUCCINATE, D- (UNII: BVK87L5TNB) (.ALPHATOCOPHEROL, D UNII:N9PR3490H9)	.ALPHATOCOPHEROL CALCIUM SUCCINATE, D-	10 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	20 ug
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	75 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	2.5 mg
RIBOFLAVIN (UNII: TLM29760FR) (RIBOFLAVIN - UNII:TLM29760FR)	RIBOFLAVIN	1.6 mg
NIACINAMIDE (UNII: 25X5118RD4) (NIACINAMIDE - UNII:25X5118RD4)	NIACINAMIDE	16.3 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1667 ug
THIAMINE (UNII: X66NSO3N35) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1.4 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE ACETATE (UNII: 3J2P07GVB6)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Packaging

;	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NHRIC:28595-715-30	30 in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
dietary supplement		03/28/2024	

Supplement Facts			
Serving Size :		Serving per Container :	
	Amount Per Serving	% Daily Value	
color			
shape			
size (solid drugs)	11 mm		
imprint			
scoring	1		