

MINCORA- vitamin tablet, coated
Allegis Pharmaceuticals, LLC

Mincora Tablets

Supplement Facts

Supplement Facts		
Serving Size: 1 Tablet		
Servings per container: 30		
Amount Per Serving:		
		% Daily Value
Folate (from 1,000 mcg folic acid)	1667 mcg DFE	417%
Vitamin B6 (as Pyridoxine HCl)	10 mg	500%
Vitamin B12 (as cyanocobalamin)	4.5 mcg	188%
Vitamin D3 (as Cholecalciferol)	20 mcg	100%
N-Acetyl-L-Cysteine	150 mg	*

*Daily Values (DV) not established.

Other Ingredients:

Microcrystalline cellulose, powder cellulose, vegetable stearic acid, silica, croscarmellose sodium, vegetable magnesium stearate, hydroxypropyl methylcellulose (HPMC), titanium oxide.

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 obscure pernicious anemia in that hematologic remission can occur while neurological manifestations progress. Mincora Tablets should only be used under the direction and supervision of a licensed medical practitioner.

Contraindications

Mincora Tablets are contraindicated in patients with a known hypersensitivity to any of the contained ingredients. Do not take this product if you are presently taking mineral oil, unless directed by 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

Dosage and Administration

Description: Mincora Tablets is a prescription dietary supplement intended for oral administration.

Indication and Usage: Mincora Tablets is to provide significant amounts of Vitamins B6, B12, D3, and folate to supplement the diet, and to help assure that nutritional deficiencies of these vitamins will not develop.

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

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 is broken or missing.

Statements

† 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

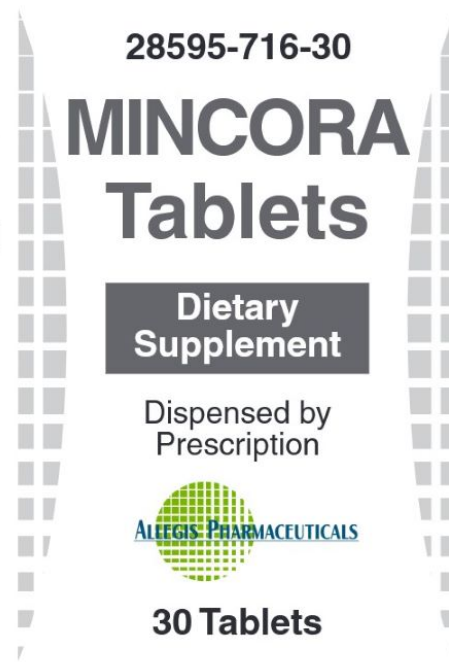
Usual Dosage: Usual adult dose is one tablet daily, or as prescribed by a licensed medical practitioner.

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

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.

Manufactured in the USA for:
Allegis Pharmaceuticals, LLC
Canton, MS 39046
Rev. 10/2024



Supplement Facts

Serving Size: 1 Tablet
Servings per container: 30

Amount Per Serving:		% Daily Value
Folate (from 1,000 mcg folic acid)	1667 mcg DFE	417%
Vitamin B6 (as Pyridoxine HCl)	10 mg	500%
Vitamin B12 (as cyanocobalamin)	4.5 mcg	188%
Vitamin D3 (as Cholecalciferol)	20 mcg	100%
N-Acetyl-L-Cysteine	150 mg	*

*Daily Values (DV) not established.

OTHER INGREDIENTS: Microcrystalline Cellulose, powdered cellulose, vegetable stearic acid, silica, croscarmellose sodium, vegetable magnesium stearate, hydroxypropyl methylcellulose (HPMC) and titanium dioxide.

How Supplied

Mincora Tablets: Each bottle contains 30 tablets (white) (28595-716-30)

Mincora Tablets are available as white, round tablets with F100 imprint and are available in 30 count bottles (28595-716-30)

These Statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease.

Manufactured in the USA for:

Allegis Pharmaceuticals, LLC

Canton, MS 39046

MINCORA

vitamin tablet, coated

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:28595-716
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	4.5 ug
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	20 ug
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	10 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1667 ug
N-ACETYL-L-CYSTEINE 2-DEOXY-3-THIO-D-ERYTHRO-PENTONIC ACID .GAMMA.-LACTONE THIOETHER (UNII: KX2B81V402) (N-ACETYL-L-CYSTEINE 2-DEOXY-3-THIO-D-ERYTHRO-PENTONIC ACID .GAMMA.-LACTONE THIOETHER - UNII:KX2B81V402)	N-ACETYL-L-CYSTEINE 2-DEOXY-3-THIO-D-ERYTHRO-PENTONIC ACID .GAMMA.-LACTONE THIOETHER	150 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE ACETATE (UNII: 3J2P07GVB6)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
HYDROXYPROPYL METHYLCELLULOSE (UNII: 3NXW29V3WO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:28595-716-30	30 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
dietary supplement		01/06/2025	

Supplement Facts

Serving Size : **Serving per Container :**

Amount Per Serving **% Daily Value**

color

shape	
size (solid drugs)	11 mm
imprint	
scoring	1

Labeler - Allegis Pharmaceuticals, LLC (792272861)

Revised: 1/2025

Allegis Pharmaceuticals, LLC