

**RELCARE- vitamin tablet, coated**  
**Allegis Pharmaceuticals, LLC**

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**Relcare Tablets**

**Supplement Facts**

<b>Supplement Facts</b>		
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 megnesium stearate, hydroxypropyl methylcellulose (HPMC), titanium oxide.

**Precautions**

Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamine 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. Relcare Tablets should only be used under the direction and supervision of a licensed medical practitioner.

**Contraindications**

Relcare Tablets are contraindicated in patients with a know 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:** Relcare Tablets is a prescription dietary supplement intended for oral administration.

**Indication and Usage:** Relcare 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, Inc.  
Canton, MS 39046  
Rev. 03/2025



28595-719-30

# REL CARE Tablets

**Dietary  
Supplement**

Dispensed by  
Prescription



**30 Tablets**

## 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%
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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

Relcare Tablets: Each bottle contains 30 tablets (white) (28595-719-30)

Relcare Tablets are available as white, round tablets with F100 imprint and are available in 30 count bottles (28595-719-30)

**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

Rev 03/2025

## REL CARE

vitamin tablet, coated

### Product Information

<b>Product Type</b>	DIETARY SUPPLEMENT	<b>Item Code (Source)</b>	NHRIC:28595-719
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CYANOCOBALAMIN</b> (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	4.5 ug
<b>N-ACETYL-L-CYSTEINE 2-DEOXY-3-THIO-D-ERYTHRO-PENTONIC ACID .GAMMA.-LACTONE THIOETHER</b> (UNII: KX2B81V402) (N-ACETYL-L-	N-ACETYL-L-CYSTEINE 2-DEOXY-3-THIO-D-ERYTHRO-	150 mg

CYSTEINE 2-DEOXY-3-THIO-D-ERYTHRO-PENTONIC ACID .GAMMA.-LACTONE THIOETHER - UNII:KX2B81V402)	PENTONIC ACID .GAMMA.-LACTONE THIOETHER	150 mg
<b>CHOLECALCIFEROL</b> (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	20 ug
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	10 mg
<b>FOLIC ACID</b> (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1667 ug

Inactive Ingredients

Ingredient Name	Strength
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>POWDERED CELLULOSE</b> (UNII: SMD1X3XO9M)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>SILICA</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>HYDROXYPROPYL METHYLCELLULOSE</b> (UNII: 3NXW29V3WO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:28595-719-30	30 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
dietary supplement		04/16/2025	

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)

Establishment

Name	Address	ID/FEI	Business Operations
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Formulation Technology Incorporated		062525910	manufacture
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Revised: 4/2025

Allegis Pharmaceuticals, LLC