

VYLARIS- vylaris tablet
Oncora Pharma, LLC

Vylaris Tablets

STATEMENT OF IDENTITY

Vylaris Tablets 85477-0912-30

Dietary Supplement

Dispensed by Prescription[†]

Vylaris capsules are an orally administered prescription vitamin formulation for the clinical dietary management of suboptimal nutritional status in patients where advanced supplementation is required and for patients with occasional constipation to restore and maintain regularity.

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

Vylaris is manufactured in accordance with Current Good Manufacturing Practice for foods, using ingredients that have been approved by the U.S. Food and Drug Administration (FDA) as food additives or are "Generally Recognized as Safe" (GRAS) for their intended use.

DOSAGE

Take two tablets once or twice daily with 8-12 oz of water or as directed by a healthcare practitioner.

SAFE HANDLING

CONTRAINDICATIONS

This product is contraindicated in patients with a known hypersensitivity to any of the ingredients. Vylaris is contraindicated in patients with hypercalcemia, malabsorption syndrome, abnormal sensitivity to the toxic effects of vitamin D, and hypervitaminosis D.

WARNINGS AND PRECAUTIONS

Tell your doctor if you have kidney problems or thyroid disease. Do not use this product if you have abdominal pain, diarrhea, or loose stools. Rectal bleeding and/or failure to have a bowel movement after the use of a laxative formula may be an indication of a more serious condition. Should this occur, or if you have a known medical condition and are taking this medication, consult your healthcare provider about the risks and benefits

prior to taking this or any dietary supplement.

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.

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 Oncora Pharma, LLC, at 1-844-551-9911.

KEEP OUT OF REACH OF CHILDREN

STORAGE

Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature.]

HOW SUPPLIED HEALTH CLAIM

Vylaris, Metabolic Support

Dietary Supplement

Vegan tablets are light brown and have an oval shape

Bottles contain 30 Tablets 85477-912-30

Manufactured in USA for:

Oncora Pharma, LLC

Dallas TX 75228

Rev. 05/2026

*Oncora Pharma does not represent these product codes to be National Drug Codes (NDC). Product codes are formatted according to standard industry practice, to meet the formatting requirement by pedigree reporting and supply-chain control including pharmacies.


Dispensed by Prescription[†]All prescriptions using this product shall be pursuant to state statutes as applicable. This is not an Orange Book product. This product may be administered only under a physician's supervision.

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 (Rx). 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 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)

Vylaris

<p>DOSAGE AND ADMINISTRATION: Usual adult dosage is 2 tablets by mouth once or twice daily or as directed by a licensed medical practitioner.</p>	<p>NDC 85477-912-30 Rx Only</p>	<p>SUPPLEMENTAL FACTS Serving size: 2 Tablets Servings per container: 15</p> <table border="1"> <thead> <tr> <th>Amount Per Serving:</th> <th colspan="2">% Daily Value</th> </tr> </thead> <tbody> <tr> <td>Vitamin D (as cholecalciferol)</td> <td>250 mcg (10,000 IU)</td> <td>1250%</td> </tr> <tr> <td>Folate (from 2000 mcg folic acid)</td> <td>3,400 mcg DFE</td> <td>850%</td> </tr> <tr> <td>Inulin (from organic agave (heart) extract) 1,000 mg *</td> <td></td> <td>*</td> </tr> <tr> <td>Slippery Elm (bark)</td> <td>850 mg</td> <td>*</td> </tr> <tr> <td>Aloe Vera (leaf)</td> <td>450 mg</td> <td>*</td> </tr> <tr> <td>Cascara sagrada (bark)</td> <td>270 mg</td> <td>*</td> </tr> </tbody> </table> <p>*Daily value not established</p>	Amount Per Serving:	% Daily Value		Vitamin D (as cholecalciferol)	250 mcg (10,000 IU)	1250%	Folate (from 2000 mcg folic acid)	3,400 mcg DFE	850%	Inulin (from organic agave (heart) extract) 1,000 mg *		*	Slippery Elm (bark)	850 mg	*	Aloe Vera (leaf)	450 mg	*	Cascara sagrada (bark)	270 mg	*	
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<p>IF YOU ARE PREGNANT OR NURSING A BABY, ASK A HEALTH PROFESSIONAL BEFORE USING THIS PRODUCT.</p> <p>KEEP THIS PRODUCT OUT OF REACH OF CHILDREN. In case of accidental overdose, call a doctor or poison control center immediately. 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.</p>		<p>Other Ingredients: Stearic Acid, Calcium Carbonate, Di-Calcium Phosphate, Magnesium stearate</p>	<p>Lot: Exp:</p>																					
<p>Dispense by Prescription 30 Tablets</p>		<p>Distributed by: Oncora Pharma Dallas, TX 75228 © 2026 Oncora Pharma</p>																						

pdp

VYLARIS			
vylaris tablet			
Product Information			
Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:85477-912
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
BLUE AGAVE INULIN (AGAVE TEQUILANA) (UNII: PW973NF38H) (BLUE AGAVE INULIN (AGAVE TEQUILANA) - UNII:PW973NF38H)	BLUE AGAVE INULIN (AGAVE TEQUILANA)	500 mg
ELM (UNII: 63POE2M46Y) (ELM - UNII:63POE2M46Y)	ELM	425 mg
ALOE FEROX LEAF (UNII: 0D145J8EME) (ALOE FEROX LEAF - UNII:0D145J8EME)	ALOE FEROX LEAF	225 mg
RHAMNUS CATHARTICA BARK (UNII: KD27950XHY) (RHAMNUS CATHARTICA BARK - UNII:KD27950XHY)	RHAMNUS CATHARTICA BARK	135 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	.125 mg

Inactive Ingredients	
Ingredient Name	Strength
CELLULOSE ACETATE (UNII: 3J2P07GVB6)	
CALCIUM STEARATE (UNII: 776XM7047L)	
CALCIUM PHOSPHATE (UNII: 97Z1W3NDX)	
SILICA (UNII: ETJ7Z6XBU4)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:85477-912-30	30 in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		05/01/2026	

Supplement Facts	
Serving Size :	Serving per Container :
Amount Per Serving	% Daily Value
color	
scoring	1
shape	
size (solid drugs)	26 mm

Labeler - Oncora Pharma, LLC (119482542)