

**HYLAVITE- thiamine, riboflavin, niacin, vitamin b6, folic acid, vitamin b12, biotin, pantothenic acid, vitamin c tablet, coated**  
**AMELLA PHARMA, LLC**

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**HYLAVITE**

**HYLAVITE Tablets Dietary Supplement**  
**Dispensed by Prescription†**

<b>Supplement Facts</b>		
Serving Size: 1 Tablet		Serving per container: 30
<b>Amount Per Serving</b>		<b>% Daily Value</b>
Vitamin C (as ascorbic Acid)	100 mg	167%
Thiamine (as thiamine mononitrate)	1.5 mg	100%
Riboflavin	1.7 mg	100%
Niacin (as niacinamide)	20 mg	100%
Vitamin B6 (as pyridoxine HCl)	10 mg	500%
Folic Acid	1 mg	250%
Vitamin B12 (as methylcobalamin)	6 mcg	100%
Biotin	300 mcg	100%
Pantothenic Acid (as d-calcium pantothenate)	10 mg	100%

**OTHER INGREDIENTS:** Microcrystalline Cellulose, Croscarmellose Sodium, Pharmaceutical Glaze, Mono- and Diglycerides, Starch, Calcium Stearate.

**DESCRIPTION**

HYLAVITE Tablets is an orally administered prescription vitamin formulation for the clinical dietary management of suboptimal nutritional status in patients where advanced folate supplementation is required and nutritional supplementation in physiologically stressful conditions for maintenance of good health is needed.

HYLAVITE is a small, round, yellow, clear-coated tablet, with debossed "A" on one side.

**CONTRAINDICATIONS**

This product is contraindicated in patients with known hypersensitivity to any of the ingredients.

**PRECAUTIONS**

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

HYLAVITE Tablets should only be used under the direction and supervision of a licensed medical practitioner. Use with caution in patients that may have a medical condition, are pregnant, lactating, trying to conceive, under the age of 18, or taking medications.

Folic acid supplementation may obscure pernicious anemia, in that hematologic remission can occur while neurological manifestations progress.

**Keep out of reach of children.**

**Pregnancy and Lactation:**

HYLAVITE Tablets is not intended for use in pregnant or lactating patients

**ADVERSE REACTIONS**

Allergic sensitizations have been reported following oral administration of folic acid. Consult your physician immediately if adverse side effects occur.

## **DOSAGE AND ADMINISTRATION**

Usual adult dose is 1 tablet by mouth once or twice daily or as prescribed by a licensed medical practitioner.

## **HOW SUPPLIED HEALTH CLAIM:**

HYLAVITE Tablets are supplied as a small, round, yellow, clear-coated tablet, with debossed "A" on one side.

HYLAVITE Tablets is available as the following:  
72287-221-30\* 30ct bottle

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]

Manufactured for:  
Amella Pharma, LLC  
E Brunswick, NJ 08816

Call your doctor for medical advice about side effects. You may report side effects to Amella Pharma, LLC at 1-844-385-0850.

Issued: 11/2018 AP2002v3

\*Amella 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.

† 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). 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.

## **Packaging**

USUAL DOSAGE: Usual adult dose is 1 tablet by mouth once daily or as prescribed by a licensed medical practitioner. If you are pregnant or nursing, ask a healthcare professional prior to using. Consult your physician immediately if adverse side effects occur.

KEEP 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.]

10/2018 AP-2001v2



Manufactured for: Amella Pharma, LLC  
East Brunswick, NJ 08816 1-844-385-0850

72287-0221-30

# HYLAVITE Tablets



30 Tablets

Rx Only

## Supplement Facts

Serving Size: 1 Tablet

Amount Per Serving:	% Daily Value	
Vitamin C (as ascorbic acid).....	100 mg	167%
Thiamine (as thiamine mononitrate).....	1.5 mg	100%
Riboflavin.....	1.7 mg	100%
Niacin (as niacinamide).....	20 mg	100%
Vitamin B6 (as pyridoxine HCl).....	10 mg	500%
Folic Acid.....	1 mg	250%
Vitamin B12 (as methylcobalamin).....	6 mcg	100%
Biotin.....	300 mcg	100%
Pantothenic Acid (as d-calcium pantothenate).....	10 mg	100%

OTHER INGREDIENTS: microcrystalline cellulose, croscarmellose sodium, pharmaceutical glaze, mono- and diglycerides, starch, calcium stearate.



VARNISH FREE ZONE FOR EXPIRATION AND LOT #

## HYLAVITE

thiamine, riboflavin, niacin, vitamin b6, folic acid, vitamin b12, biotin, pantothenic acid, vitamin c tablet, coated

### Product Information

<b>Product Type</b>	DIETARY SUPPLEMENT	<b>Item Code (Source)</b>	NHRIC:72287-221
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	100 mg
<b>THIAMINE MONONITRATE</b> (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1.5 mg
<b>RIBOFLAVIN</b> (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	1.7 mg
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	20 mg
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	10 mg
<b>FOLIC ACID</b> (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
<b>METHYLCOBALAMIN</b> (UNII: BR1SN1JS2W) (METHYLCOBALAMIN - UNII:BR1SN1JS2W)	METHYLCOBALAMIN	6 ug
<b>BIOTIN</b> (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)	BIOTIN	300 ug
<b>PANTOTHENIC ACID</b> (UNII: 19F5HK2737) (PANTOTHENIC ACID - UNII:19F5HK2737)	PANTOTHENIC ACID	10 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>CALCIUM STEARATE</b> (UNII: 776XM7047L)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:72287-221-30	30 in 1 BOTTLE		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
dietary supplement		09/26/2018	

**Supplement Facts****Serving Size :** **Serving per Container :**

	Amount Per Serving	% Daily Value
color		
shape		
size (solid drugs)	11 mm	
scoring	1	
imprint		

**Labeler** - AMELLA PHARMA, LLC (081189492)

Revised: 12/2018

AMELLA PHARMA, LLC