

HYLAZINC- zinc, ascorbic acid, thiamine, riboflavin, niacinamide, pyridoxine, folic acid, methylcobalamin, tablet, coated
AMELLA PHARMA, LLC

HYLAZINC

HYLAZINC Tablets Dietary Supplement
Dispensed by Prescription†

Supplement Facts			
Serving Size: 1 Tablet		Servings per container: 100	
Amount Per Serving			% Daily Value
Zinc (as Zinc Citrate)	50 mg		455%
Vitamin C (as Ascorbic Acid)	100 mg		111%
Thiamine (as Thiamine Mononitrate)	1.5 mg		125%
Riboflavin	1.7 mg		131%
Niacin (as Niacinamide)	20 mg		125%
Vitamin B6 (as Pyridoxine HCl)	10 mg		588%
Folate	1666 mcg DFE (1 mg Folic Acid)		417%
Vitamin B12 (as Methylcobalamin)	6 mcg		250%

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

DESCRIPTION

HYLAZINC 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.

HYLAZINC is a small, round, yellow with yellow specks, clear-coated tablet, with debossed "A2" 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.

HYLAZINC 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:

HYLAZINC 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:

HYLAZINC Tablets are supplied as a small, round, yellow with yellow specks, clear-coated tablet, with debossed "A2" on one side.

HYLAZINC Tablets is available as the following:

72287-0651-01* 100ct 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: 09/2020 AP9002v1

*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.

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)

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 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.]

72287-0651-01

HYLAZINC Tablets



100 Tablets

Rx Only

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



06/2020 AP9001v1

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

HYLAZINC

zinc, ascorbic acid, thiamine, riboflavin, niacinamide, pyridoxine, folic acid, methylcobalamin, tablet, coated

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:72287-651
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC CITRATE (UNII: K72I3DEX9B) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	50 mg
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	100 mg
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1.5 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	1.7 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	20 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1B16Z)	PYRIDOXINE HYDROCHLORIDE	10 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
METHYLCOBALAMIN (UNII: BR1SN1JS2W) (METHYLCOBALAMIN - UNII:BR1SN1JS2W)	METHYLCOBALAMIN	6 ug

Inactive Ingredients

Ingredient Name	Strength
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
SHELLAC (UNII: 46N107B710)	
STARCH, CORN (UNII: O8232NY3SJ)	
CALCIUM STEARATE (UNII: 776XM7047L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NHRIC:72287-651-01	100 in 1 BOTTLE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
dietary supplement		09/10/2020		

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: 9/2020

AMELLA PHARMA, LLC