

AMLADEX- vitamin c, d3, b1, b6, b12, folate, nadh, coenzyme q-10 tablet
Misemer Pharmaceuticals, Inc.

AmladexTablets

HEALTH CLAIM:

Amladex Tablets Dietary Supplement

Dispensed by Prescription†

Supplement Facts

Serving Size: 1 Tablet Servings per Bottle: 30		
Amount Per Serving:	% Daily Value	
Vitamin C (as ascorbic acid)	125 mg	208%
Vitamin D3 (as cholecalciferol)	500 IU	125%
Vitamin B1 (as Thiamin HCl)	25 mg	1,667%
Vitamin B6 (as pyridoxal phosphate anhydrous)	12.5 mg	625%
Folic Acid	1.667 mg	250%
Vitamin B12 (as methylcobalamin)	1 mg	16,667%
NADH (reduced nicotinamide-adenine dinucleotide)	5 mg	*
CoEnzyme Q-10 (ubiquinone)	50 mg	*
<i>*Daily Values (DV) not established.</i>		

OTHER INGREDIENTS: Microcrystalline Cellulose, Croscarmellose Sodium, Silicon Dioxide, Magnesium Stearate..

DESCRIPTION:

Amladex 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.

Amladex should be administered under the supervision of a licensed medical practitioner.

WARNING AND PRECAUTIONS

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

Amladex 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.

DOSAGE & ADMINISTRATION

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

INDICATIONS AND USAGE

Amladex 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.

HOW SUPPLIED HEALTH CLAIM:

Amladex is supplied as a clear coated oblong tablet dispensed in HDPE plastic bottles of 30ct.

Dispensed by Prescription[†]

Reserved for Professional Recommendation

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. There are no implied or explicit claims on therapeutic equivalence.

† 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)

Manufactured for:

Misemer Pharmaceuticals, Inc.

Ripley, MS 38663


Rev. 11/21

STORAGE AND HANDLING:

Store at controlled room temperature 15°-30°C (59°F-86°F). Keep in cool dry place. Call your doctor about side effects. You may report side effects to FDA at 1-800-FDA-1088.

KEEP THIS OUT OF THE REACH OF CHILDREN.

Non Varnished area
for online printing



0276-0709-30


SUPPLEMENT FACTS
Serving Size: 1 Tablet
Servings Per Container: 30

Amount Per Serving	% Daily Value
Vitamin C (as ascorbic acid)	125mg 139%
Vitamin D3 (as cholecalciferol)	12.5mcg 63%
Vitamin B1 (as thiamine HCl)	25mg 2083%
Vitamin B6 (as pyridoxal 5' phosphate)	12.5mg 735%
Folate (from 1mg Folic Acid)	1.667mg DFE 41.7%
Vitamin B12 (as methylcobalamin)	1mg 41667%
NADH (reduced nicotinamide adenine dinucleotide)	5mg *
Coenzyme Q-10 (ubiquinone)	50mg *

* Daily values not established

Other ingredients: Microcrystalline Cellulose, Pregelatinized Starch, Coating (Beta-Carotene, Titanium Dioxide, Hypromellose, Polyvinyl Alcohol, Polyethylene Glycol, Taic), Croscarmellose Sodium, Silica, Silicon Dioxide, Hydroxypropyl Cellulose, Magnesium Stearate.

Manufactured for:
Miseimer Pharmaceutical, Inc
Ripley, MS 38863




Made in the USA

AMLADEX

Dispensed by Prescription

Lot:
Exp:



3 02760 70930 9

30 Tablets

Dietary Supplement

AMLADEX

vitamin c, d3, b1, b6, b12, folate, nadh, coenzyme q-10 tablet

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:0276-0709
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	125 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	12.5 ug
THIAMINE HYDROCHLORIDE (UNII: M572600E5P) (THIAMINE ION - UNII:4ABTOJ945J)	THIAMINE HYDROCHLORIDE	25 mg
PYRIDOXAL PHOSPHATE ANHYDROUS (UNII: F06SGE49M6) (PYRIDOXAL PHOSPHATE ANHYDROUS - UNII:F06SGE49M6)	PYRIDOXAL PHOSPHATE ANHYDROUS	12.5 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1.667 mg
METHYLCOBALAMIN (UNII: BR1SN1JS2W) (METHYLCOBALAMIN - UNII:BR1SN1JS2W)	METHYLCOBALAMIN	1 mg
NADH (UNII: 4J24DQ0916) (NADH - UNII:4J24DQ0916)	NADH	5 mg
COENZYME Q10, (2Z)- (UNII: U705VLF0VW) (COENZYME Q10, (2Z)- - UNII:U705VLF0VW)	COENZYME Q10, (2Z)-	50 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:0276-0709-30	30 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
dietary supplement		11/01/2021	

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

	Amount Per Serving	% Daily Value
color		
shape		
size (solid drugs)	19 mm	
scoring	1	

Labeler - Misemer Pharmaceuticals, Inc. (784121365)

Revised: 11/2021

Misemer Pharmaceuticals, Inc.