

DALIVIT- ascorbic acid, folic acid, niacinamide, thiamine hydrochloride, riboflavin, pyridoxine hydrochloride, cyanocobalamin and calcium pantothenate capsule, coated
Taleos Pharma

DALIVIT Softgels

Rx Only

DESCRIPTION

DALIVIT is a prescription multi-vitamin in the form of a red, oval, softgel.

INDICATION AND USAGE

DALIVIT is a prescription multi-vitamin supplement that can be taken to improve nutritional status in conditions requiring dietary supplementation. DALIVIT can also be used for the dietary management of individuals with distinct nutritional needs under a physician or healthcare provider's supervision for end stage failure, dialysis, hyperhomocysteinemia or inadequate dietary vitamin intake.

CONTRAINDICATIONS

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

WARNING

Folic Acid in doses above 0.1 mg daily may obscure pernicious anemia in that hematological remission can occur while neurological manifestations remain progressive. Folic Acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B12 is deficient.

DO NOT EXCEED RECOMMENDED DOSAGE.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

PRECAUTIONS

Folic Acid in doses above 0.1 mg daily may obscure pernicious anemia in that hematological remission can occur while neurological manifestations remain progressive. The 1 mg of cyanocobalamin contained in DALIVIT Softgels has been shown to provide an adequate amount of cyanocobalamin to address this precaution. A safer upper limit of 100 mg per day has been established for the unsupervised medical use of pyridoxine. Consider all sources of pyridoxine supplementation when prescribing DALIVIT Softgels.

If pregnant, or planning to become pregnant or are currently breast-feeding please contact your physician, or healthcare provider before using or continuing use of this medication.

ADVERSE REACTIONS

Allergic sensitization has been reported following both oral and parenteral administration of folic acid. Paresthesia and somnolence have been reported with the use of pyridoxine hydrochloride. Mild transient diarrhea, polycythemia vera, peripheral vascular thrombosis, itching transitory exanthema and feeling of swelling of the entire body has been associated with the use of cyanocobalamin.

DRUG INTERACTIONS

Pyridoxine supplements should not be given to patients receiving the drug levodopa, because the action of levodopa is antagonized by pyridoxine. However, pyridoxine may be used concurrently in patients receiving a preparation containing both carbidopa and levodopa. Concurrent use of phenytoin and folacin (folic acid) may result in decreased phenytoin effectiveness.

DOSAGE AND ADMINISTRATION

Adults: One Softgel taken orally daily or as directed by a physician.

DO NOT EXCEED RECOMMENDED DOSAGE.

Supplement Facts

Serving Size: 1 Softgel

Servings per
Container: 30

Amount Per Serving	% Daily Value	
Vitamin C (as Ascorbic Acid)	100mg	167%
Folic Acid	1mg	250%
Vitamin B1 (as Thiamine HCl)	2mg	133%
Vitamin B2 (as Riboflavin)	2mg	117%
Vitamin B3 (as Niacinamide)	20mg	100%
Vitamin B6 (as Pyridoxine HCl)	10mg	400%
Vitamin B12 (as Cyanocobalamin)	1mg	16,667%
Pantothenic Acid (as Calcium Pantothenate)	10mg	100%

STORAGE

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

Protect from light and moisture.

Dispense in a well-closed, tight, light-resistant container as defined by the USP using a child resistant closure.

HOW SUPPLIED

DALIVIT softgels are supplied as red softgel. DALIVIT softgels are available in bottles of 30 (70877-8243-3). Each softgel of Dalivit contains 100 mg ascorbic acid, 1 mg of Folic Acid, 2 mg of thiamine hydrochloride, 2 mg of riboflavin, 20 mg of niacinamide, 10 mg of pyridoxine hydrochloride, 1 mg of cyanocobalamin, and 10 mg of calcium pantothenate.

Distributed By:

Taleos Pharma Corp.

Eatontown, NJ 07724

www.taleos-pharma.com

PRINCIPAL DISPLAY PANEL - 30 Softgel Bottle Label

70877-8243-3

DALIVIT

PRESCRIPTION

MULTI-VITAMINS

Rx Only 30 SOFTGELS

DIETARY SUPPLEMENT

DOSAGE AND ADMINISTRATION: Adults: One Softgel taken orally daily or as directed by a physician.

NDC 70877-8243-3

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

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Distributed By: Taleos Pharma Corp.
Eatontown, NJ 07724 www.taleos-pharma.com



MADE IN USA



Lot No.

Exp. Date:

Rx Only 30 SOFTGELS
DIETARY SUPPLEMENT

Supplement Facts

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Other Ingredients: Medium Chain Triglycerides, Bovine Gelatin, Glycerin, Yellow Beeswax, Purified Water, Sunflower Lecithin, Titanium Dioxide, FD&C Red, FD&C Blue.

DALIVIT

ascorbic acid, folic acid, niacinamide, thiamine hydrochloride, riboflavin, pyridoxine hydrochloride, cyanocobalamin and calcium pantothenate capsule, coated

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:70877-8243
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	100 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
THIAMINE HYDROCHLORIDE (UNII: M572600E5P) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE HYDROCHLORIDE	2 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	2 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	20 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1B16Z)	PYRIDOXINE HYDROCHLORIDE	10 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	1 mg
CALCIUM PANTOTHENATE (UNII: 568ET80C3D) (PANTOTHENIC ACID - UNII:19F5HK2737, CALCIUM CATION - UNII:2M83C4R6ZB)	PANTOTHENIC ACID	10 mg

Inactive Ingredients

Ingredient Name	Strength
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
GLYCERIN (UNII: PDC6A3C0OX)	
YELLOW WAX (UNII: 2ZA36H0S2V)	

WATER (UNII: 059QF0KO0R)

LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:70877-8243-3	30 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		03/09/2018	

Supplement Facts

Serving Size : **Serving per Container :**

	Amount Per Serving	% Daily Value
color		
scoring	1	
shape		
size (solid drugs)	10 mm	

Labeler - Taleos Pharma (080318529)

Revised: 4/2018

Taleos Pharma