TALIVA- folic acid, pyridoxine hydrochloride, cyanocobalamin, doconexent, icosapent, omega-3 fatty acids, and .beta.-sitosterol capsule, gelatin coated Taleos Pharma

TALIVA Softgels

Rx Only

DESCRIPTION

TALIVA is a prescription multi-vitamin in the form of a red, opaque softgel.

INDICATION AND USAGE

TALIVA is a prescription multi-vitamin supplement with DHA and EPA that can be taken to improve nutritional status in conditions requiring Essential Fatty Acid, Vitamin B12 and B6 and Folic Acid supplementation capsule.

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.

Ingestion of more than 3 grams of omega-3 fatty acids per day has been shown to have potential antithrombotic effects, including increased bleeding time and INR. Administration of omega-3 fatty acids should be avoided in patients on anticoagulants and in those known to have an inherited or acquired bleeding diathesis.

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.

ADVERSE REACTIONS

Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

DOSAGE AND ADMINISTRATION

Adults

One to four softgels orally daily or as directed by a physician.

Supplement Facts

Serving Size: 1 Softgel Servings per Container: 60 **Amount Per Serving**

| 1mg |
|--------|
| 12.5mg |
| 0.5mg |
| 500mg |
| 350mg |
| 35mg |
| 200mg |
| |

^{*} AbsoFolTM, under exclusive license, is trademark of Taleos Pharma Corp. (patents pending)

STORAGE

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

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

HOW SUPPLIED

TALIVA softgels are supplied as red, opaque, oblong, coated softgels. TALIVA softgels are available in bottles of 60 (NDC: 70877-8588-01).

Distributed By:

Taleos Pharma Corp.

Eatontown, NJ 07724

www.taleos-pharma.com

TALIVA, ABSOFOL and TALEOS are trademarks of Taleos Pharma Corp.

PRINCIPAL DISPLAY PANEL - 60 Softgel Bottle Label

70877-8588-1

TALIVA

PRESCRIPTION MULTI-VITAMINS

WITH DHA/EPA

WITH 100%

AbsoFol

Rx Only

DIETARY SUPPLEMENT

60 Softgels

 $\begin{array}{l} \textbf{DOSAGE AND ADMINISTRATION:} \ Adults - \ Take \ one \ to \ four \\ softgels \ orally \ daily \ or \ as \ directed \ by \ a \ physician. \ See \\ product \ literature \ for \ full \ prescribing \ information. \end{array}$

STORAGE:Store at 20°-25°C (68°-77°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.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN

Taliva™ is a trademark of Taleos Pharma Corp.

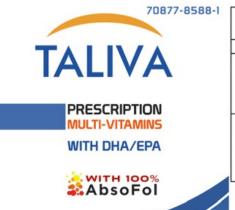
† AbsoFol™, under exclusive license, is trademark of Taleos Pharma Corp. (patents pending)

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

MADE IN USA



Lot No. TA2846A Exp. Date: 12/2019



RX Only

DIETARY SUPPLEMENT 60 Softgels

| Amount Per Serving | % Daily Valu |
|--|--------------|
| Folic Acid (as Folic Acid - AbsoFol™)† | 1mg |
| Vitamin B6 (as Pyridoxine HCI) | 12.5mg |
| Vitamin B12 (as Cyanocobalamin) | 0.5mg |
| Omega-3 Acids | 500mg |
| Doconexent(DHA) | 350mg |
| Icosapent (EPA) | 35mg |
| Beta-sitosterol | 200mg |

Other Ingredients:Bovine Gelatin, Glycerin, White Beeswax, Purified Water, Soy Lecithin, Titanium Dioxide, FD&C Red #40, Ascorbic Acid, Ascorbyl Palmitate and Mixed Tocopherols.

TALIVA

folic acid, pyridoxine hydrochloride, cyanocobalamin, doconexent, icosapent, omega-3 fatty acids, and .beta.-sitosterol capsule, gelatin coated

| Product Information | | | | | |
|-------------------------|--------------------|--------------------|------------------|--|--|
| Product Type | DIETARY SUPPLEMENT | Item Code (Source) | NHRIC:70877-8588 | | |
| Route of Administration | ORAL | | | | |

| Active Ingredient/Active Moiety | | | | |
|--|-----------------------------|----------|--|--|
| Ingredient Name | Basis of Strength | Strength | | |
| Folic Acid (UNII: 935E97BOY8) (Folic Acid - UNII:935E97BOY8) | Folic Acid | 1 mg | | |
| Pyridoxine Hydrochloride (UNII: 68Y4CF58BV) (Pyridoxine - UNII:KV2JZ1BI6Z) | Pyrido xine Hydro chlo ride | 12.5 mg | | |
| Cyanocobalamin (UNII: P6 YC3EG204) (Cyanocobalamin - UNII:P6 YC3EG204) | Cyanocobalamin | 0.5 mg | | |
| Doconexent (UNII: ZAD9OKH9JC) (Doconexent - UNII:ZAD9OKH9JC) | Doconexent | 350 mg | | |
| Icosapent (UNII: AAN7QOV9EA) (Icosapent - UNII:AAN7QOV9EA) | Icosapent | 35 mg | | |
| Omega-3 Fatty Acids (UNII: 71M78END5S) (Omega-3 Fatty Acids - UNII:71M78END5S) | Omega-3 Fatty Acids | 35 mg | | |
| .BetaSitosterol (UNII: S347WMO6M4) (.BetaSitosterol - UNII:S347WMO6M4) | .BetaSito stero l | 200 mg | | |

| Inactive Ingredients | | |
|---|----------|--|
| Ingredient Name | Strength | |
| Gelatin, Unspecified (UNII: 2G86QN327L) | | |
| Glycerin (UNII: PDC6A3C0OX) | | |
| White Wax (UNII: 7G1J5DA97F) | | |
| Water (UNII: 059QF0KO0R) | | |
| Lecithin, Soybean (UNII: 1DI56QDM62) | | |
| Titanium Dioxide (UNII: 15FIX9 V2JP) | | |
| FD&C Red NO. 40 (UNII: WZB9127XOA) | | |
| Ascorbic Acid (UNII: PQ6CK8PD0R) | | |
| Ascorbyl Palmitate (UNII: QN83US2B0N) | | |
| Tocopherol (UNII: R0ZB2556P8) | | |

| Packaging | | | | | | |
|-----------------------|------------------|-------------------------------|-------------|-----------------|------|--------------------|
| # | Item Code | Package Description | Marketii | ng Start Date | Ma | arketing End Date |
| ı NH | RIC:70877-8588-1 | 60 in 1 BOTTLE | | | | |
| | | | | | | |
| | | | | | | |
| Marketing Information | | | | | | |
| VId. | | | | | _ | |
| | keting Category | Application Number or Monogra | ph Citation | Marketing Start | Date | Marketing End Date |

| Supplement Facts | | | | |
|--------------------|---------------------------|-------------------------|--|--|
| Serving Size : | | Serving per Container : | | |
| | Amount Per Serving | % Daily Value | | |
| color | | | | |
| scoring | 1 | | | |
| shape | | | | |
| size (solid drugs) | 25 mm | | | |

Labeler - Taleos Pharma (080318529)

Revised: 1/2018 Taleos Pharma