

LUVIRA- luvira capsule
Sterling-Knight Pharmaceuticals, LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).

Luvira Capsules

ΩOmega-3-acid

Dietary Supplement

Dispense by Prescription

DESCRIPTION

Luvira is an orally administered prescription omega-3-acid dietary supplement formulation for the clinical dietary management of suboptimal nutritional status in patients where advanced supplementation is required and nutritional supplementation in physiologically stressful conditions for maintenance of good health is needed.

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

SUPPLEMENT FACTS

Serving Size: 1 Capsule

Servings Per Container:90

Amount Per Serving % Daily Value

Total Omega-3-Acid 1220mg*

Eicosapentaenoic acid (EPA) 465 mg

Docosahexaenoic acid(DHA) 375 mg

*Daily values not established

Other Ingredients: Gelatin (bovine), glycerin, de-ionized water.

INDICATIONS AND USAGE

Luvira is an orally administered prescription omega-3-acid formulation for the clinical dietary management of suboptimal nutritional status in patients where advanced supplementation is required and nutritional supplementation in physiologically stressful conditions for maintenance of good health is needed.

WARNINGS AND PRECAUTIONS:

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

The usual dose of Luvira is 3 - 4 capsules per day.

The daily dose may be taken as a single dose of 3 - 4 capsules or 1 – 2 capsules twice daily with or without food.

HOW SUPPLIED

Luvira is supplied as clear yellowish Softgel capsule dispensed in white HDPE plastic bottles of 90ct. 69336-349-90

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.**

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.

Manufactured for:

Sterling-Knight Pharmaceuticals, LLC

Ripley, MS 38663

Item 34990

Rev. 0620-1

Each capsule contains 1.22 grams of omega-3-acid liquid concentrate consisting of 840mg of total omega-3 fatty acids. Each capsule ingredient provides Eicosapentaenoic acid (EPA); 465mg and Docosahexaenoic acid (DHA); 375mg

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

KEEP OUT OF REACH OF CHILDREN

Patients should be advised to swallow Luvira capsules whole. Do not break open, crush, dissolve, or chew Luvira

Store at 25°C (77°F); excursions permitted to 15° - 30°C (59°-86° F) [see USP Controlled Room Temperature]. Do not freeze.

Do not accept if seal on bottle opening is missing or broken.

Lot #: Exp. Date
3 69336 34990 1 Rev.01/20

69336-349-90

Dispense by Prescription

Luvira
(omega-3 acid)

1.22 gr

Swallow capsules whole

90 Capsules Dietary Supplement

SUPPLEMENT FACTS

Serving Size: 1 capsule
Servings Per Container: 90

Amount Per Serving	% Daily Value
Total Omega-3-Acid	1220mg *
Eicosapentaenoic acid (EPA)	465mg
Docosahexaenoic acid (DHA)	375mg

* Daily values not established

Other ingredients: Gelatin (bovine), glycerin, de-ionized water

Sterling Knight
PHARMACEUTICALS

Manufactured for:
Sterling | Knight Pharmaceuticals, LLC
Ripley, MS 38663

LUVIRA

luvira capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:69336-349
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
OMEGA-3 FATTY ACIDS (UNII: 71M78END5S) (OMEGA-3 FATTY ACIDS - UNII:71M78END5S)		OMEGA-3 FATTY ACIDS	1220 mg	
12-HYDROXYEICOSAPENTAENOIC ACID, (12R)- (UNII: 78P2ZC128S) (12-HYDROXYEICOSAPENTAENOIC ACID, (12R)- - UNII:78P2ZC128S)		12-HYDROXYEICOSAPENTAENOIC ACID, (12R)-	465 mg	
4,7,10,13,16,19-DOCOSAHEXAENOIC ACID, (4E,7E,10E,13E,16E,19E)- (UNII: ZR7NX0Z98X) (4,7,10,13,16,19-DOCOSAHEXAENOIC ACID, (4E,7E,10E,13E,16E,19E)- - UNII:ZR7NX0Z98X)		4,7,10,13,16,19-DOCOSAHEXAENOIC ACID, (4E,7E,10E,13E,16E,19E)-	375 mg	
Inactive Ingredients				
Ingredient Name		Strength		
GELATIN (UNII: 2G86QN327L)				
GLYCERIN (UNII: PDC6A3C0OX)				
Product Characteristics				
Color	yellow	Score	no score	
Shape	capsule	Size	78mm	
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69336-349-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/17/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		01/17/2020		

Labeler - Sterling-Knight Pharmaceuticals, LLC (079556942)

Establishment

Name	Address	ID/FEI	Business Operations
Sterling-Knight Pharmaceuticals, LLC		079556942	manufacture(69336-349)

Revised: 1/2020

Sterling-Knight Pharmaceuticals, LLC