

HYDROPHOR- petrolatum ointment

Geritrex LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Hydrophor Ointment

Drug Facts

Active Ingredients: Petrolatum 42%

Purpose: Skin protectant

Uses

- Rehydrates dry, chapped or chafed skin.
- May be used alone as a skin lubricant or protectant.

Directions

Apply generously to affected areas or as directed by your physician.

Apply generously to affected area

Warnings

For External Use Only.

When using this product:

- Avoid contact with eyes.
- If the condition worsens, discontinue use and contact a physician.

Inactive Ingredient

Ceresin, Lanolin Alcohol,
Microcrystalline Wax, Mineral Oil,
Phenoxyethanol

Store at room temperature (59°F-86°F).

KEEP OUT OF REACH OF CHILDREN.



NDC 54162-500-01

HydrophorTM Ointment

Colorless • Water Absorbent • Dry Skin Lubricant

FOR EXTERNAL USE ONLY
NET WT. 1 LB. (454g)

Drug Facts
Active Ingredients: Purpose Petrolatum 42%.....Skin protectant
Uses ■ Helps prevent and protects chapped, chapped or cracked skin. ■ Helps prevent and protect from the drying effects of wind and cold weather.
Warnings For External Use Only. When using this product: ■ Avoid contact with eyes. ■ If the condition worsens, discontinue use and contact a physician. ■ KEEP OUT OF REACH OF CHILDREN.
Directions ■ Apply generously to affected areas or as directed by your physician.
Other information Store at room temperature 15°-30°C (59° F-86° F).
Inactive Ingredients Ceresin Wax, Lanolin, Alcohol, Mineral Oil, Paraffin Wax, Phenoxyethanol.

Distributed by Geritrex, LLC
144 Kingsbridge Road East
Mount Vernon, NY 10550
1-800-736-3437
www.geritrex.com

HP16.11

HYDROPHOR

petrolatum ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54162-500
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	42 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CERESIN (UNII: Q1LS2UJO3A)	
LANOLIN ALCOHOLS (UNII: 884C3FA9HE)	
PARAFFIN (UNII: I9O0E3H2ZE)	
MINERAL OIL (UNII: T5L8T28FGP)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54162-500-01	454 g in 1 JAR; Type 0: Not a Combination Product	07/31/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	07/31/2015	

Labeler - Geritrex LLC (112796248)**Registrant** - Geritrex LLC (112796248)

Establishment

Name	Address	ID/FEI	Business Operations
Geritrex LLC		112796248	manufacture(54162-500)

Revised: 1/2018

Geritrex LLC