HYDROPHOR- hydrophor ointment Akron Pharma Inc.

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.

Drug Facts

Active Ingredient:

Petrolatum 42%

Purpose:

Skin protectant

Uses

- Helps prevent and protects chafed, 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.

Inactive Ingredient

Ceresin Wax, Lanolin, Mineral Oil, Paraffin Wax & Phenoxyethanol.

Other Information

• Store at room temperature 15°-30°C (59°F-86°F).

Questions?

Please Call 1(877) 225-6999

Manufactured for:

Akron Pharma, Inc. Fairfield, NJ 07004

Manufactured in U.S.A

olntment helps protect and soothe with a unique blend of ing Ideal for use on the hands, elbows and feet as well as i dry areas of the skin needing additional protection.	at helps to ance-free gredients	(P)	NDC 71		g Facts ingredient:	Purpose	
dry areas of the skin needing additional protection.		Akrain Pharm	8	Petrolati Uses	um 42%	Skin Protectar	
	•	HYDROP	HOR	Warnin	event and protects chafed, chapped event and protect from the drying eff ogs	ects of wind and cold weather.	
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Akron Pharma Inc, Fairtleid, NJ-07004 1 (877) 225-6999 www.akronpharma.com				 If the cor 	ndition worsens, discontinue use and OUT OF REACH OF CHILDR	l contact a physician. EN	
		Soothes & Protects E *Compare to Aquaphor* Oi		Apply ge Other in	enerously to affected areas or as dire formation		
N 71399 51012 9		Net Wt. 3.5oz (100)	g)	Inactive	oom temperature 15°C- 30°C (59°F-8 ingredients /ax, Lanolin Alcohol, Mineral Oli, Par		
		NDC 71399-5101-1			Drug Facts		
HYDROPHOR OINTMENT is an effective skin protectant that helps to restore and protect very dry, damaged skin. This unique, fragrance-free oIntment helps protect and soothe with a unique blend of ingredients.				Active ingredient: Purpos			
		Akrán Pharma		Petrolatum 42%Skin Protect Uses • Helps prevent and protects chafed, chapped or cracked skin.		Skin Protectant	
			IIIa	Helps prevent an	d protects chafed, chapped or cra d protect from the drying effects of	acked skin. of wind and cold weather.	
Ideal for use on the hands, elbows and feet as wel dry areas of the skin needing additional protection	n.	HYDROPHOR Warnings For External Use only When using this product					
The product is not manufactured or distributed by the owner of the registered trademark Aquaphor*			Avoid		n using this product: id contact with eyes. e condition worsens, discontinue use and contact a physician.		
Manufactured for: Akron Pharma Inc, Fairfield, NJ-07004					KEEP OUT OF REACH OF CHILDREN		
1 (877) 225-6999 www.akronpharma.com		Soothes & Protects D	ory Skin		pply generously to affected areas or as directed by your physician.		
		*Compare to Aquaphor [®] Oir	Itment	Store at room tem	perature 15°C- 30°C (59°F-86°F)		
3 71399 51011 2		Net Wt. 16oz (45	i4g)	Ceresin Wax, Land	blin Alcohol, Mineral Oil, Parraffin	Wax & Phenoxyethanol.	
Product Information							
	ΙΠΙΜΑΝΙ	OTC DBUC	Ham Cada ()	2	NDC-71	1200 E101	
Product Type		MAN OTC DRUG Item Code (Source)		1100.71	NDC:71399-5101		
Route of Administration	TOPICA	CAL					
Active Ingredient/Active	Moiety						
	Ingredient I	Name		Basis	Basis of Strength Strengt		
PETROLATUM (UNII: 4T6H12B)	N9U) (PETROLA	TUM - UNII:4T6H12BN9	U)	PETRO	LATUM	42 g in 100 g	
Inactive Ingredients							
Ingredient Name						Strength	
CERESIN (UNII: Q1LS2UJO3A)							
LANOLIN (UNII: 7EV65EAW6H)							
MINERAL OIL (UNII: T5L8T28F	GP)						
	40.077237						
PARAFFIN (UNII: 1900E3H2ZE)	492ZZ31)						
PHENOXYETHANOL (UNII: HIE							
PHENOXYETHANOL (UNII: HIE	Package	Description	Mark	eting Start	t Date Mark	eting End Date	
PHENOXYETHANOL (UNII: HIE Packaging # Item Code	_	Description ot a Combination Produc		-	t Date Mark	eting End Date	
PHENOXYETHANOL (UNII: HIE- Packaging # Item Code 1 NDC:71399-5101-1 454 g in 1	1 JAR; Type 0: N		ct 02/03/2	.020	t Date Mark	eting End Date	

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC monograph final	part347	02/03/2020					

Labeler - Akron Pharma Inc. (067878881)

Registrant - Akron Pharma Inc. (067878881)

Establishment

Name	Address	ID/FEI	Business Operations
SLV PHARMACEUTICALS LLC		081225162	manufacture(71399-5101)

Revised: 10/2019

Akron Pharma Inc.