

ARUMACIL- dimethicone, petrolatum ointment
Hyatt Life Sciences, 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.

Arumacil

Drug Facts

Active ingredients

Dimethicone 1.1%

Petrolatum 92.8%

Purpose

Skin Protectant

Use

- relieves dryness and softens cold sores and fever blisters

Warnings

For external use only

When using this product

- do not get into eyes

Stop use and ask a doctor if

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days

Do not use on

- deep or puncture wounds
- animal bites
- serious burns

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away

Directions

- apply as needed

Inactive ingredients

Arum Palaestinum, Beta-Sitosterol, Peganum Harmala, Turmeric, Vanillin, Vitamin C

Package Labeling:

<p>DISTRIBUTED BY HYATT LIFE SCIENCES, INC. 101 S. BROADWAY, STERLING, KS 67579 TO REPORT A SERIOUS ADVERSE EVENT, CONTACT: 1-620-204-7160.</p> <p>CAUTION: CONTENTS MAY STAIN CLOTHES.</p>	<p>  Arumacil™ Petrolatum and Dimethicone Skin Protectant Cold Sore Ointment Net Wt. 0.26 oz (7.5 g)</p>	<p>Drug Facts</p> <table border="1"><thead><tr><th>Active ingredients</th><th>Purpose</th></tr></thead><tbody><tr><td>Dimethicone 1.1%)</td><td>.....Skin Protectant</td></tr><tr><td>Petrolatum 92.8%)</td><td></td></tr></tbody></table> <p>Use ■ relieves dryness and softens cold sores and fever blisters</p> <p>Warnings For external use only When using this product ■ do not get into eyes</p>	Active ingredients	Purpose	Dimethicone 1.1%)Skin Protectant	Petrolatum 92.8%)		<p>Drug Facts (continued)</p> <p>Stop use and ask a doctor if ■ condition worsens ■ symptoms last more than 7 days or clear up and occur again within a few days</p> <p>Do not use on ■ deep or puncture wounds ■ animal bites ■ serious burns</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away</p> <p>Directions ■ apply as needed</p> <p>Inactive ingredients Arum Palaestinum, Beta-Sitosterol, Peganum Harmala, Turmeric, Vanillin, Vitamin C</p>
Active ingredients	Purpose								
Dimethicone 1.1%)Skin Protectant								
Petrolatum 92.8%)									
		 8 10492 03021 4							

PETROLATUM AND DIMETHICONE SKIN
PROTECTANT COLD SORE OINTMENT
KEEP OUT OF REACH OF CHILDREN.

THIS UNIT NOT LABELED FOR RETAIL SALE. SEE OUTER CONTAINER FOR COMPLETE DRUG FACTS INFORMATION.
ACTIVE INGREDIENTS: DIMETHICONE 1.1% AND PETROLATUM 92.8%. PURPOSE: SKIN PROTECTANT.
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ARUMACIL

dimethicone, petrolatum ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72933-000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	11 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	928 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ARUM PALAESTINUM WHOLE (UNII: 4E96UIB20M)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
TURMERIC (UNII: 856YO1Z64F)	
VANILLIN (UNII: CH1530446X)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72933-000-00	1 in 1 BOX	04/01/2019	
1		7.5 g in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	04/01/2019	

Labeler - Hyatt Life Sciences, Inc. (117495900)

Revised: 10/2021

Hyatt Life Sciences, Inc.