

**ALBOTHYL- policresulen solution solution**  
**OASIS TRADING**

*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](#).*

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**Policresulen**

Oral debriding agent/oral wound cleanser for temporary use to cleanse canker sores and minor wounds or minor gum inflammation resulting from minor dental procedures, dentures, orthodontic appliances, accidental injury, or other irritations of the mouth and gums such as mouth burns, cheek bites and toothbrush abrasions. Cleans minor mouth wounds by removing foreign materials that can impede the healing process.

Keep out of reach of children

**Adults and children 2 years of age and older:** rinse half of a capful around in the mouth over affected area for at least 1 minute, then spit out. Use up to 4 times daily after meals and at bedtime or as directed by a dentist or physician. Children under 12 years of age should be supervised in the use of the product. Children under 2 years of age: consult a dentist or physician. To open child safety cap, squeeze smooth sides while turning. Reclose tightly.

For buccal use only.

Do not use in the eyes by putting this product into the rectum by using fingers or any mechanical device or applicator.

Ask a doctor before use if you have a vaginal discharge, rectal bleeding, diaper rash.

When using this product consult a doctor before exceeding recommended dosage.

Stop use and ask a doctor if condition gets worse, condition persists for more than 7 days, condition clears up and occurs again with within a few days. Do not begin to use any other hydrocortisone product unless you have consulted a doctor.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Water

For buccal use only

# ALBOTHYL

<b>Drug Facts</b>	
<b>Active Ingredients (in 1g)</b> Polycresulen Solution 720mg -----	<b>Purpose</b> anti-inflammatory
<b>Uses</b> <p>■ Oral debriding agent/oral wound cleanser for temporary use to cleanse canker sores and minor wounds or minor gum inflammation resulting from minor dental procedures, dentures, orthodontic appliances, accidental injury, or other irritations of the mouth and gums such as mouth burns, cheek bites and toothbrush abrasions. Cleans minor mouth wounds by removing foreign materials that can impede the healing process.</p>	
<b>Warnings</b> <p>For buccal use only.            Do not use in the eyes by putting this product into the rectum by using fingers or any mechanical device or applicator.  <b>Ask a doctor before use if you have</b> a vaginal discharge, rectal bleeding, diaper rash.  <b>When using this product</b> consult a doctor before exceeding recommended dosage.  <b>Stop use and ask a doctor if</b> condition gets worse, condition persists for more than 7 days, condition clears up and occurs again with within a few days. Do not begin to use any other hydrocortisone product unless you have consulted a doctor.  <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</p>	
<b>Directions</b> <p>■ <b>Adults and children 2 years of age and older:</b> rinse half of a capful around in the mouth over affected area for at least 1 minute, then spit out. Use up to 4 times daily after meals and at bedtime or as directed by a dentist or physician. Children under 12 years of age should be supervised in the use of the product. Children under 2 years of age: consult a dentist or physician. To open child safety cap, squeeze smooth sides while turning. Reclose tightly.</p>	
<b>Other Information</b> <p>■ Store at controlled room temperature 20-25 degrees C (68-77 degrees F).</p>	
<b>Inactive Ingredient</b> Water	
<b>Questions or comments?</b> Call weekdays from 9 a.m to 5 p.m EST at (201) 669-8405 <b>Distributed By: P&amp;K FRONTIER MARKETING CORP.</b> 329 BROAD AVENUE # 2F, PALISADES PARK, NJ 07650, USA <b>Made in South Korea</b>	

# ALBOTHYL

polycresulen solution solution

Product Information			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72689-0040
<b>Route of Administration</b>	BUCCAL, VAGINAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
POLICRESULEN (UNII: 6I19M5GB0G) (POLICRESULEN - UNII:6I19M5GB0G)		POLICRESULEN	720 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72689-0040-1	5 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2018	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/21/2018	

**Labeler** - OASIS TRADING (689991468)

**Registrant** - OASIS TRADING (689991468)

## Establishment

Name	Address	ID/FEI	Business Operations
OASIS TRADING		689991468	manufacture(72689-0040) , relabel(72689-0040)