ADULT ACNOMEL TINTED- resorcinol 2% sulfur 8% cream
Denison Pharmaceuticals, 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.

Adult Acnomel (Tinted)

ACTIVE INGREDIENT

Active ingredients.....Purpose

Resorcinol 2% .....Acne Treatment ointment

Sulfur 8 % ..... Acne Treatment

DOSAGE

cover the entire affected area with a thin layer one to three times daily.

Uses

- for the treatment of acne
- clears up most acne pimples
- helps prevent new acne pimples

For external use only

Do not use on:

- broken skin
- large areas of the body

When using this product

- Apply only to areas with acne
- Rinse right away with water it it gets in eyes
- skin irritation and dryness are more likely to occur if you use another topical acne medication at the same time. If irritation occurs, use only one topical acne medication at a time.

Stop use and ask doctor if

skin irritation occurs or gets worse

Keep out of reach of children.

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

Directions

- Clean the skin throughly before applying this product
- Cover the entire affected area with a thin layer one to three times daily
- Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor.

- If bothersome dryness or peeling occur, reduce application to once a day or every other day

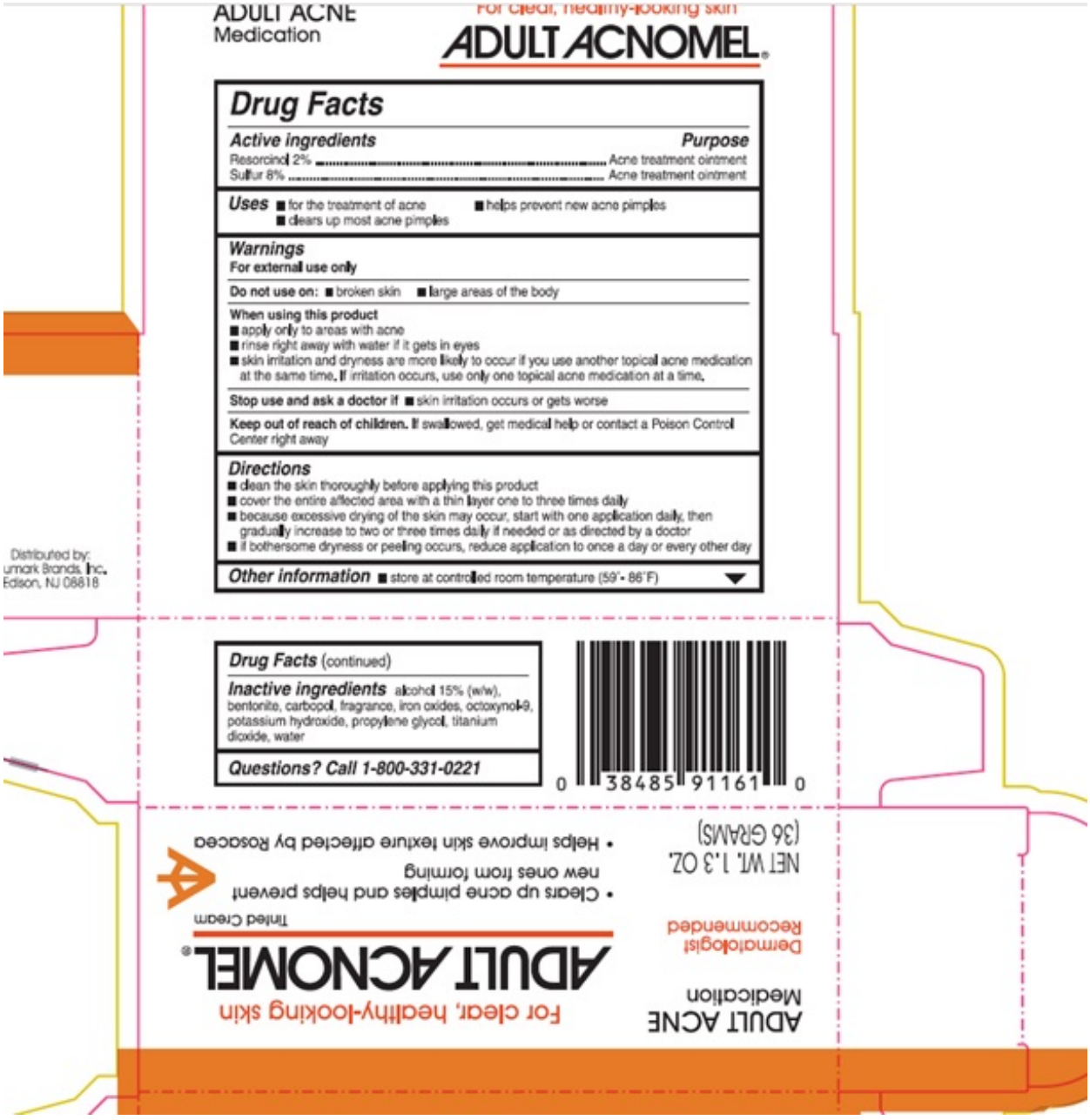
Other Information

- store at controlled room temperature (59° - 86°F)

Inactive Ingredients

alcohol 15% (w/w), bentonite, carpobol, fragrance, iron oxides, octoxynol-9, potassium hydroxide, propylene glycol, titanium dioxide, water

Label



ADULT ACNOMEL TINTED

resorcinol 2% sulfur 8% cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0295-9116
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
RESORCINOL (UNII: YUL4LO94HK) (RESORCINOL - UNII:YUL4LO94HK)	RESORCINOL	2 g in 100 g
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	8 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
BENTONITE (UNII: A3N5ZCN45C)	
BROWN IRON OXIDE (UNII: 1N032N7MFO)	
OCTOXYNOL 9 (UNII: 7JPC6Y25QS)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0295-9116-01	7 g in 1 PACKAGE; Type 0: Not a Combination Product	01/01/2017	
2	NDC:0295-9116-09	36 g in 1 PACKAGE; Type 0: Not a Combination Product	01/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	01/01/2017	

Labeler - Denison Pharmaceuticals, Inc. (001207208)

Establishment

Name	Address	ID/FEI	Business Operations
Denison Pharmaceuticals, Inc.		001207208	manufacture(0295-9116)

Revised: 11/2018 Denison Pharmaceuticals, Inc.