

ADULT ACNOMEL- resorcinol, sulfur cream
NUMARK BRANDS, 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 Ingredients

Active Ingredients	Purpose
Resorcinol 2%	Acne treatment ointment
Sulfur 8%	Acne treatment ointment

Uses

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

Warnings

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
- do not get into eyes. If excess skin irritation develops or increases, discontinue use and consult a doctor
- 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 a 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 thoroughly 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 occurs, 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, carbopol, fragrance, iron oxides, octoxynol-9, potassium hydroxide, propylene glycol, titanium dioxide, water

Questions? Call 1-800-331-0221

PRINCIPAL DISPLAY PANEL

30% More

ADULT ACNE
Medication

For clear, healthy-looking skin

ADULT ACNOMEL®
Tinted Cream

- Effective treatment for adult acne & blemishes
- Helps improve skin texture affected by Rosacea
- Less drying- does not contain Benzoyl Peroxide

Dermatologist Recommended

- Clears up acne pimples and helps prevent new ones forming
- Helps improve skin texture affected by Rosacea

NET WT. 1.3 OZ.
(36 GRAMS)

Distributed by:

Numark Brands
27070 Miles Rd,
Solon OH 44139

G10004
Rev 7/19

30%
More

ADULT ACNE
Medication

For clear, healthy-looking skin
ADULT ACNOMEL®

Tinted Cream

- Effective treatment for adult acne & blemishes
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010004
Rev 2/19

ADULT ACNE
Medication

Dermatologist
Recommended

NET WT. 1.3 OZ.
(36 GRAMS)

For clear, healthy-looking skin
ADULT ACNOMEL®

Tinted Cream

- Clears up acne pimples and helps prevent new ones from forming
- Helps improve skin texture affected by Rosacea



Drug Facts (continued)

Inactive ingredients: alcohol 17% (v/v), benzoin, cinnol, propyl glycol, octylalcohol, polybutene-1, propylene glycol, stearic acid, water

Questions? Call 1-800-214-2379

Drug Facts

Active Ingredients: Benzoyl peroxide 2%
Sulfur 2%
Acne treatment ointment

Purpose: Acne treatment ointment

Uses: ■ for the treatment of acne ■ helps prevent new acne pimples
■ clears up most acne pimples

Warnings: 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
■ do not get into eyes. If excess skin irritation develops or increases, discontinue use and consult a doctor
■ 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 a 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 thoroughly 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 occurs, reduce application to once a day or every other day

Other information: ■ store at controlled room temperature (59° - 86°F)

Do not use on:
broken skin
large areas of the body

ADULT ACNOMEL®
For clear, healthy-looking skin

ADULT ACNE
Medication

30% More

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Medication

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D14048 Rev 7/19

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D14048 Rev 7/19

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ADULT ACNE
Medication

For clear, healthy-looking skin
ADULT ACNOMEL®

Tinted Cream

NET WT. 1.3 OZ. (36 GRAMS)



Drug Facts- Active Ingredients: Resorcinol 2%, Sulfur 8%. **Purpose:** Acne treatment ointment. **Uses:** For the treatment and prevention of acne pimples. **Warnings:** For external use only. Apply only to areas with acne. Do not use on broken skin or apply to large areas of the skin. Rinse right away with water if it gets in the eyes. Stop use and ask a doctor if skin irritation occurs or gets worse. Skin irritation and dryness are more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time. **Keep this and all medication out of the reach of children.** In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. **Directions:** Cleanse the skin thoroughly before applying medication 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 occurs, reduce application to once a day or every other day.~~ Store at controlled room temperature (59° - 86°F). **Inactive Ingredients:** alcohol 15% (w/w), bentonite, carbopol, fragrance, iron oxides, octoxynol-9, potassium hydroxide, propylene glycol, titanium dioxide, water.

ADULT ACNOMEL
resorcinol, sulfur cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69846-911
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
RESORCINOL (UNII: YUL4LO94HK) (RESORCINOL - UNII:YUL4LO94HK)	RESORCINOL	20 mg in 1 g
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	80 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
BENTONITE (UNII: A3N5ZCN45C)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
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:69846-911-61	1 in 1 CARTON	10/08/1946	
1		36 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/08/1946	

Labeler - NUMARK BRANDS, INC (080184668)**Establishment**

Name	Address	ID/FEI	Business Operations
Dhaliwal Pharmaceuticals Laboratories, LLC		116933772	manufacture(69846-911)