

CARING MILL ACNE SPOT TREATMENT- sulfur cream

Clixit, Llc

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.

caring mill™ Acne Spot Treatment

Drug Facts

Active Ingredient

Sulfur 10%

Purpose

Acne Treatment

Use:

For the treatment of acne

Warnings:

For external use only.

When using this product

- Do not use on broken skin or large areas of skin
- Apply only to areas with acne
- Skin irritation and dryness is 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
- Stop use and ask a doctor if skin irritation occurs or gets worse
- Rinse right away with water if product gets in eyes

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

Directions:

- Clean the skin thoroughly before using
- Apply a thin layer to entire affected area
- 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 Ingredients:

Aqua (Deionized Water), Camphor, Carbomer, Isopropyl Alcohol, Phenoxyethanol, Propylene Carbonate, Salicylic Acid, Tetrasodium EDTA, Triethanolamine, Zinc Oxide.

HELPS CLEAR BLEMISHES FAST

Benefits

- Reduces redness and swelling
- Controls oil production
- Allows skin to heal
- Unblocks clogged pores
- Prevents new breakouts
- Will not cause redness or irritation

Results may vary

Maximum sulfur 10% penetrates pores to control acne

Camphor instantly cools and calms inflamed skin

Salicylic acid unblocks pores and sheds dead skin cells for faster healing

NOT TESTED ON ANIMALS

Made in the USA

Manufactured for **FSA Store Inc.**

240 W 37th St. 6th Floor

New York, NY 10018

Customer Help Line:

(844) 425-4948

Packaging

INNER PACKAGE LABEL



Acne Spot Treatment

with sulfur 10%

HELPS CLEAR BLEMISHES FAST

0.50 fl. oz. (15 mL)

- Apply only to areas with acne. ■ Do not use on broken skin or large areas of skin. ■ Using other topical acne medications at the same time may increase dryness or irritation of the skin.
- If bothersome dryness or peeling occurs, reduce application to once per day. ■ Stop use and ask a doctor if skin irritation occurs or gets worse. ■ Rinse right away with water if product gets in eyes.

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

Directions:

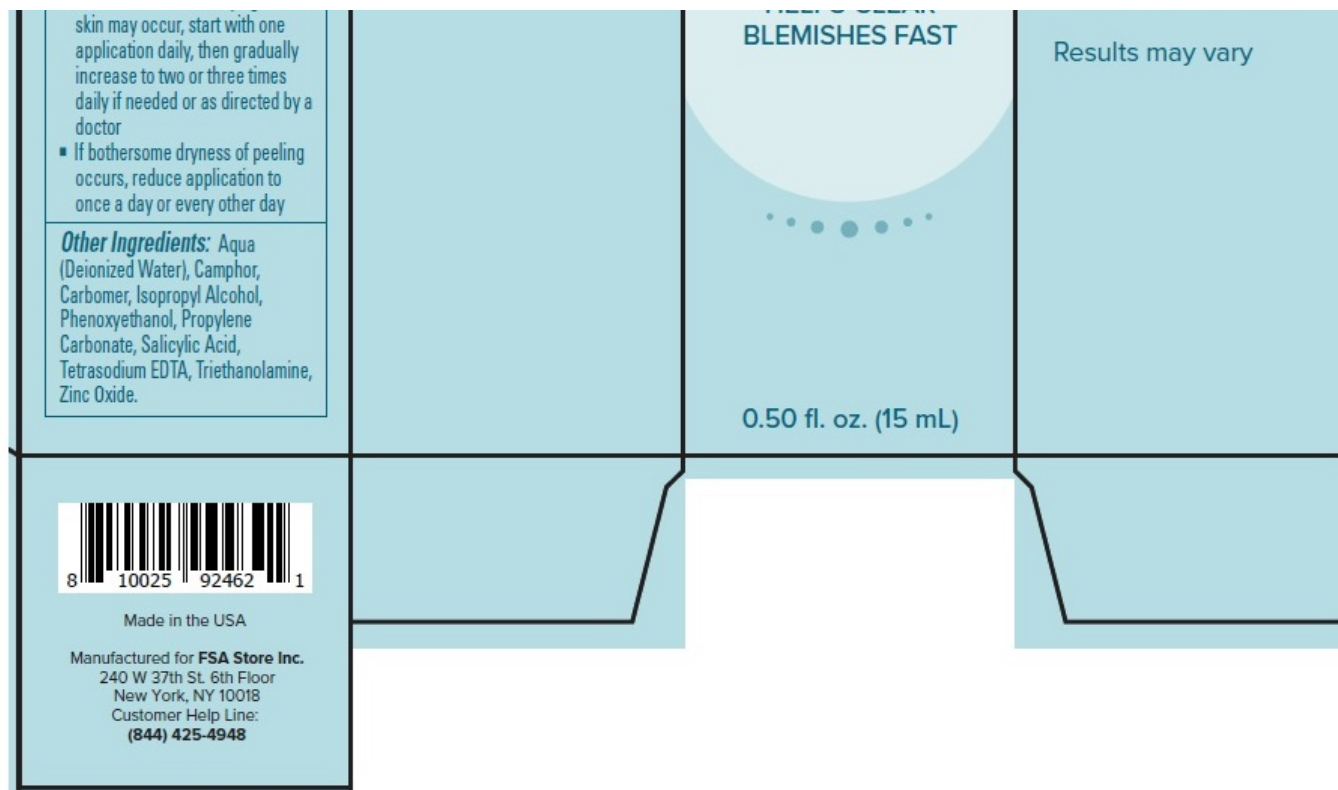
- Clean skin thoroughly before using.
- Apply a thin layer to the entire affected area.
- Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor.

Other Ingredients: Aqua (Deionized Water), Camphor, Carbomer, Isopropyl Alcohol, Phenoxyethanol, Propylene Carbonate, Salicylic Acid, Tetrasodium EDTA, Triethanolamine, Zinc Oxide.

**Results may vary.*

OUTER PACKAGE LABEL

<div> <h3>Drug Facts</h3> <table> <tr> <th>Active Ingredient</th> <th>Purpose</th> </tr> <tr> <td>Sulfur 10%</td> <td>Acne Treatment</td> </tr> </table> <p>Use: For the treatment of acne</p> <p>Warnings: For external use only.</p> <p>When using this product</p> <ul style="list-style-type: none"> ■ Do not use on broken skin or large areas of skin ■ Apply only to areas with acne ■ Skin irritation and dryness is 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 ■ Stop use and ask a doctor if skin irritation occurs or gets worse ■ Rinse right away with water if product gets in eyes <p>Keep out of reach of children. If swallowed, get medical help or call a Poison Control Center right away.</p> <p>Directions:</p> <ul style="list-style-type: none"> ■ Clean the skin thoroughly before using ■ Apply a thin layer to entire affected area ■ Because excessive drying of the </div>	Active Ingredient	Purpose	Sulfur 10%	Acne Treatment	<p>Maximum sulfur 10% penetrates pores to control acne</p> <p>Camphor instantly cools and calms inflamed skin</p> <p>Salicylic acid unblocks pores and sheds dead skin cells for faster healing</p> <div> </div>	<div> <p>caring mill™</p> <h2>Acne Spot Treatment</h2> <p>with sulfur 10%</p> <div> <p>HELPS CLEAR</p> </div> </div>	<h3>Benefits</h3> <ul style="list-style-type: none"> • Reduces redness and swelling • Controls oil production • Allows skin to heal • Unblocks clogged pores • Prevents new breakouts • Will not cause redness or irritation
Active Ingredient	Purpose						
Sulfur 10%	Acne Treatment						



CARING MILL ACNE SPOT TREATMENT

sulfur cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71328-062
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	100 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PHENOXYETHANOL (UNII: H1E492ZZ3T)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
EDETATE SODIUM (UNII: MP1J8420LU)	
TROLAMINE (UNII: 9O3K93S3TK)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

Product Characteristics

Color	yellow	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71328-062-02	1 in 1 BOX	06/21/2021	
1	NDC:71328-062-01	15 mL 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 final	part333D	06/21/2021	

Labeler - Clixit, Llc (014971694)

Revised: 6/2021

Clixit, Llc