SULFADERM- sulfur ointment
Pharmadel 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.

Sulfaderm Acne Treatment Sulfur 10%

Drug Facts

Drug Facts

Active ingredient & Purpose

Active ingredient	***Purpose***
Sulfur 10%	Acne treatment

Uses

For the treatment of acne. Clears up acne:
- blemishes
- pimples
- blackheads
- whiteheads

Warnings

For external use only. Avoid contact with the eyes.

Do not use on
- broken skin
- large areas of the skin

When using this product
- 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.
- apply only to areas with acne

If pregnant or breast feeding,

ask a health professional before use

Keep out of the reach of children.

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

Directions

- cleanse 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 between (59-86°F) 15-30°C
- don’t use if clear seal over cap is broken, torn, or missing

Inactive ingredients

cetyostearyl alcohol, glycerin, glyceryl monostearate, methylparaben, mineral oil, paraffin, petrolatum, propylparaben, polyethylene

glycol, sorbitan monooleate, water

Distributed by:

Pharmadel LLC

New Castle, DE 19720

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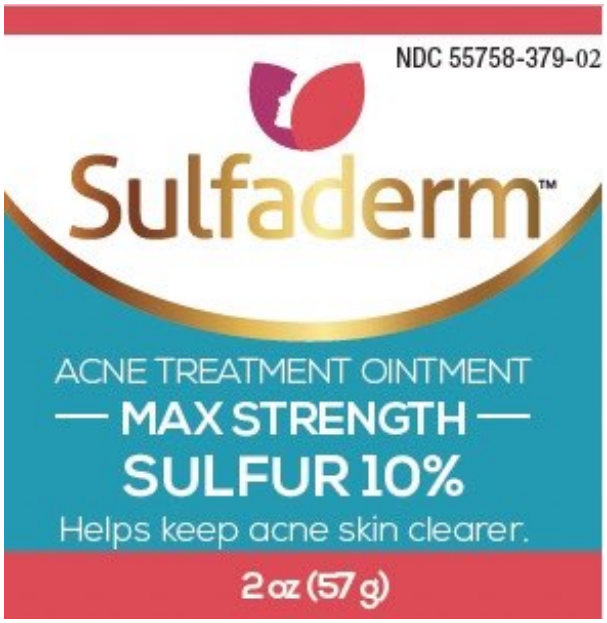
Principal Display Panel



SULFADERM

sulfur ointment

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55758-379
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	10 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PETROLATUM (UNII: 4T6H12BN9U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	

Product Characteristics

Color	yellow	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55758-379-02	57 g in 1 JAR; Type 0: Not a Combination Product	06/10/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M006	06/10/2023	

Labeler - Pharmadel LLC (030129680)

Revised: 6/2023 Pharmadel LLC