JOESOEF SKINCARE ANTI ACNE- sulfur lotion PT Galenium Pharmasia Laboratories

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.

Anti-Acne Lotion

Drug Facts

Active Ingredients Purpose

Precipitated Sulfur 6.6%.....Acne medication

Use for the treatment of acne. Penetrades pores to clear most acne blemishes, acne pimples, blackhead, and whiteheads. Helps prevent the development of new acne blemishes, blackheads, and whiteheads.

Keep out of reach of children.

In case of incidental ingestion, get medical help or contact a poison control center immediately.

Directions

- Cleanse the skin thoroughly before applying medication.
- Using a cotton swab, cover the entire effected area with a thin layer one to three times daily.
- Because excessive drying of the skim 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.
- Shake well before use

Warnings

For external use only

When using this product

- Using other topical acne medications at the same time or immediately following use of this product may increase dryness or irritation of the skin. If this occurs, only one medication should be used unless directed by a doctor.
- Do not get into eyes. If excessive skin irridation develops or increases, discontinue use and consult a doctor.

Inactive ingredients

Purified water, Ethyl alcohol, DMDM Hydantoin, Cabomer, Fragrance, Triethanolamine, Calcium oxide.



Drug Facts Active Ingredient Purpose Precipitated Sulfur 6.6%...... Acne medication Use for the treatment of acne. Penetrates pores to clear most acne blemishes, acne pimples, blackhead, and whiteheads. Helps prevent the development of new acne blemishes, blackheads, and whiteheads. Warnings For external use only When using this product • Using other topical acne medications at the same time or immediately following use of this product may increase dryness or irritation of the skin. If this occurs, only one medication should be used unless directed by a doctor. · Do not get into eyes. If excessive skin irritation develops or increases, discontinue use and consult a doctor. Keep out of reach of children. In case of accidental ingestion, get medical help or contact a poison control center immediately. Directions • Cleanse the skin thoroughly before applying medication. • Using a cotton swab, cover the entire effected 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. • Shake well before use Inactive ingredients Purified water, Ethyl alcohol, Camphor, DMDM Hydantoin, Carbomer, Fragrance, Triethanolamine, Calcium oxide. No animal testing is performed in the development of all Joesoef SKIN CARE products. www.JoesoefSkinCare.com Made in Indonesia Manufactured for Dr. Joesoef Skin Care, LLC. Distributed by Joesoef Skin Care Distributors, LLC. Boca Raton, Florida 33433 USA Joesoef SKIN CARE is a trademark of

Dr. Joesoef Skin Care, LLC

Black



Biru/TC 3402



Silver Ink



Silver Hotstamp

JOESOEF SKINCARE ANTI ACNE

sulfur lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:26050-113
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	6.6 mg in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
ALCOHOL (UNII: 3K9958V90M)		
DMDM HYDANTOIN (UNII: BYR0546TOW)		
CARBOMER 1342 (UNII: 809Y72KV36)		
TRIETHANOLAMINE BENZOATE (UNII: M3EN4GC19W)		
LIME (CALCIUM OXIDE) (UNII: C7X2M0VVNH)		

ı	Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1 NDC:26050-113-	95 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2006		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part333D	10/01/2006		

Labeler - PT Galenium Pharmasia Laboratories (726631497)

Establishment				
Name	Address	ID/FEI	Business Operations	
PT Galenium Pharmasia Laboratories		726631497	manufacture(26050-113)	

Revised: 3/2022 PT Galenium Pharmasia Laboratories