

SULFUR - sulfur soap
GRISI Hnos, S.A DE C.V

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/Ingredientes Activos

Sulfur/Azufre 10%

Purpose/Utilidad

acne/acné

Uses/Usos

For the treatment of acne, helps clear acne up acne blemishes and pimples/Para el tratamiento del acne, ayuda a eliminar y espinillas de acne

Warnings/Avisos

For external use only. Caution-if undue skin irritation develops or increases discontinue use and consult physician/Para uso externo solamente. Precaución: En caso de irritación de la piel, suspenda su uso y consulte a su médico

When using this product/Alusareste producto

- 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 / Es más probable que ocurra irritación y sequedad en la piel si se utiliza otro medicamento para el acné al mismo tiempo. Si se produce irritación, utilice únicamente un medicamento para el acné a la vez
- Apply only to the areas with acne/Aplique únicamente en áreas con acné

Do not use/No lo use

- Broken skin/Sobre heridas abiertas
- Large areas of the skin /En áreas grandes de piel

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away/Mantener fuera del alcance de los niños. En caso de ingestión, obtenga ayuda médica o contacte un centro de toxicología de inmediato.

Directions/Direcciones Wet affected area with warm water. Apply soap and make abundant suds. Leave for 10 minutes. then rinse with cold water. Repeat 2 or 3 times daily or as directed by a doctor. Not for children under 12 years. Mojar la zona afectada con agua tibia. Aplicar el jabón y obtener espuma abundante. Dejar 10 minutos. Luego lave con agua fría. Repita 2 ó 3 veces al día o seg

Inactive Ingredients: Sodium Tallowate, Sodium Cocoate, Corn (Zea Mays) Starch, Fragrance, Lanolin, Tetrasodium EDTA, Polysorbate 80.

Ingredientes Inactivos: Sebató de sodio, Cocoato de Sodio, Almidón de Maíz (Zea mays), Fragancia, Lanolina, EDTA Tetrasódico, Polisorbato 80



SULFUR

sulfur soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68437-011
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
SODIUM TALLOWATE, BEEF (UNII: 07RIK6QMEW)	
SODIUM COCOATE (UNII: R1TQH25F4I)	
STARCH, CORN (UNII: O8232NY3SJ)	
LANOLIN (UNII: 7EV65EAW6H)	
EDETATE SODIUM (UNII: MP1J8420LU)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68437-011-44	125 g in 1 BOX		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	12/01/2012	

Labeler - GRISI Hnos, S.A DE C.V (810320754)**Establishment**

Name	Address	ID/FEI	Business Operations
GRISI Hnos, S.A DE C.V		810320754	manufacture(68437-011)

Revised: 11/2012

GRISI Hnos, S.A DE C.V