

**SPAI-SONS MARIGOLD OILY SKIN- sulfur cream**  
**SPAI-SONS PHARMACEUTICAL INTERNATIONAL COSMETICS**

*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.*

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**SPAI-SONS CREMA DE CALENDULA PIEL GRASA/ MARIGOLD CREAM OILY SKIN**

Marigold extracts of medicinal plants, bio-sulfur and a selection of natural assets for the treatment of some skin rashes.

For treatment of some skin rashes that do not participate in the pathogenic microorganisms, particularly the treatment of acne.

Keep out of reach of children

Due to its composition Marigold cream is very active to normalize oily skin, hyper-secretory, body rashes, burns, or as an accelerator of wound healing, its greatest virtue is the design as an adjunct in the treatment of acne.

Avoid the contact with eyes. suspend its use if you notice an unfavorable reaction on the skin.

Apply a sufficient amount and gently spread with fingertips until the skin absorbs it. This product is for topical application

The formula includes extracts of medicinal plants and bio-sulfur, a trace element essential to cellular organization, is an asset which splits fats and regulates the secretion of the sebaceous glands, act synergistically other extracts such as healing, anti-inflammatory, antiseptic, antipuritic dermal, refreshing and soothing.

IMAGE OF THE LABEL

### CREMA CALENDULA

Como resultado de una serie de Investigaciones se logro el desarrollo de una crema emoliente con extractos botánicos de Ortiga y Caléndula. Incorporamos a la formula bio-azufre fluido para constituir un compuesto óptimo y restituir a la piel sus elementos básicos naturales que incluyen ácidos grasos, hidratantes y humectantes que aseguran una acción efectiva en la hipersecreción de las glándulas sebáceas.

**USO:** Aplicar la cantidad suficiente y frotar suavemente con la yema de los dedos para lograr su absorción. Piel hipersecretoras grasosas. Como complemento en el tratamiento del acné y suavizante de la piel

### CALENDULA CREAM

As the result of a series of Investigations, an emollient cream has been created with botanic extracts containing Nettle and Calendula. We also incorporated fluid bio-sulphur to form an optimal compound to restitute the natural basic elements of the skin which include fatty-acids to hydrate and moisturize and which will guarantee an effective action of the hyper-secretion of the sebaceous glands.

**RECOMMENDED USE:** Apply a sufficient amount and gently spread with fingertips until the skin absorbs it. Hyper-secretory oily skins. As complement of the acne treatment and skin softener.

**INGREDIENTS:**Water, ethoxydiglycol, butylene glycol, calendula officinalis flower extract, lactic acid, acrylates/acrylamide copolymer, paraffinum liquidum, polysorbate 85, glycerin,propylene glycol,propylheptyl caprylate,sodium polyacrylate, dimethicone, cyclopentasiloxane,trideceth-6, PEG/ PPG-18/18 dimethicone,urtica dioica extract, poterium officinale root extract,cinnamomun cassia extract, zingiber officinale root extract, methylparaben,propylparaben,acrylates/C10-30 alkyl acrylate crosspolymer, zinc PCA, cyclomethicone,dimethiconol, dimethicone PEG-7 isostearate, fragrance, triethanolamine, sodium methylparaben, diazolidinyl urea, allantoin, polysorbate 80,sulfur, phenoxyethanol.

Manufactured by:  
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Notif. Sanit: NSC2009CC033010

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Lote No.



SPAI SONS

# Marigold Cream

Crema de Caléndula



Piel Grasa  
Oily skin

Net Wt 2 Oz ( 60g)

## SPAI-SONS MARIGOLD OILY SKIN

sulfur cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66854-023
Route of Administration	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	0.1 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
LACTIC ACID (UNII: 33X04XA5AT)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYSORBATE 85 (UNII: A7F3N56197)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLHEPTYL CAPRYLATE (UNII: 991Z19V2OD)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CYCLOMETHICONE 5 (UNII: 0THF5PCI0R)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
URTICA DIOICA LEAF (UNII: X6M0DRN46Q)	
SANGUISORBA OFFICINALIS ROOT (UNII: 4NYV2HT01X)	
CHINESE CINNAMON (UNII: WS4CQ062KM)	
GINGER (UNII: C5529G5JPQ)	
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	
ZINC PIDOLATE (UNII: C32PQ86DH4)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
DIMETHICONOL (41 MPA.S) (UNII: 343C7U75XW)	
DIMETHICONE PEG-7 ISOSTEARATE (UNII: JVS3399FNW)	
TROLAMINE (UNII: 9O3K93S3TK)	
METHYL PARABEN SODIUM (UNII: CR6K9C2NHK)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
ALLANTOIN (UNII: 344S277G0Z)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66854-023-01	9 g in 1 JAR		
2	NDC:66854-023-02	33 g in 1 JAR		
3	NDC:66854-023-03	60 g in 1 TUBE		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph final	part358H	06/30/2012	
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**Labeler** - SPAI-SONS PHARMACEUTICAL INTERNATIONAL COSMETICS (880172184)

**Registrant** - SPAI-SONS PHARMACEUTICAL INTERNATIONAL COSMETICS (880172184)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
SPAI-SONS PHARMACEUTICAL INTERNATIONAL COSMETICS		880172184	analysis, label, manufacture, pack

Revised: 6/2012

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