

SPAI-SONS CALENDULA/MARIGOLD- calendula officinalis flower extract 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.

SPAI-SONS MARIGOLD CREAM / CREMA DE CALENDULA

SPAI-SONS MARIGOLD CREAM IS BASED IN CALENDULA OFFICINALIS EXTRACT

THE PRODUCT HAS BEEN DEVELOPED TO IMPLEMENT IN AREAS WHERE THIS FLASH,
USEFUL IN WOUND HEALING PROCESS

THIS PRODUCT KEEP OUT OF REACH OF THE CHILDREN

THIS PRODUCTT MAY BE USED IN PEOPLE WHO DO NOT SUBMIT HYPERSENSITIVITY
COMPONENTS, CAN BE USED AS A DAILY MOISTURIZING SKIN

AVOID IN TAKE OF PRODUCT, IF SO CHECK WITH YOUR DOCTOR

THE PRODUCT IS TOPICAL APPLICATION, APPLY THE AMOUNT NEEDED IN THE AREA
DESIRED

THE EXCIPIENTS CONTAINED IN THIS PRODCUT ARE PART OF A FORMULATION BASE
ON A MOISTURIZER AND CONDITIONING THE SKIN, WHICH DOES NOT GENERATE
IRRITATION, SO ITS USE IS NOT CONTRAINDICATED.

ALSO CALENDULA OFFICINALIS EXTRACT HAS OTHER NATURAL EXTRACTS THAT
HELP GIVE A BETTER FEELING IN THE SKIN.

IMAGE OF THE CARTON LABEL



SPAI-SONS CALENDULA/MARIGOLD

calendula officinalis flower extract cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66854-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD) (CALENDULA OFFICINALIS FLOWER - UNII:P0M7O4Y7YD)	CALENDULA OFFICINALIS FLOWER	20 g in 100 g
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	0.11 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A118X02B)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
LACTIC ACID (UNII: 33X04XA5AT)
DEXTROSE (UNII: IY9XDZ35W2)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
SODIUM CETOSTEARYL SULFATE (UNII: 7ZBS06BH4B)
GLYCERIN (UNII: PDC6A3C0OX)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
HAMAMELIS VIRGINIANA TOP (UNII: UDA30A2JJY)
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)
CYCLOMETHICONE (UNII: NMQ347994Z)
CHAMOMILE (UNII: FGL3685T2X)
TROLAMINE (UNII: 9O3K93S3TK)
METHYL PARABEN (UNII: A2I8C7HI9T)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
PROPYL PARABEN (UNII: Z8IX2SC1OH)

Product Characteristics

Color	brown (LIGTH BROWN)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66854-001-01	9 g in 1 JAR		
2	NDC:66854-001-03	1 in 1 BOX		
2	NDC:66854-001-02	33 g in 1 JAR		
3	NDC:66854-001-05	1 in 1 BOX		
3	NDC:66854-001-04	60 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	06/01/2004	

Labeler - SPAI SONS PHARMACEUTICAL INTERNATIONAL COSMETICS (880172184)

Registrant - SPAI SONS PHARMACEUTICAL INTERNATIONAL COSMETICS (880172184)