

**KIDS RELIEF CALENDULA- calendula officinalis, echinacea angustifolia, hypericum perforatum, phytolacca decandra, cantharis, sulphur cream**  
**HOMEOLAB USA INC**

*Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.*

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**DRUG FACTS**

**ACTIVE INGREDIENTS HPUS**

Calendula officinalis (Marigold) 1X  
Echinacea angustifolia (Coneflower) 1X  
Hypericum perforatum (St John's wort) 3X  
Phytolacca decandra (American nightshade) 3X  
Cantharis (Spanish fly) 3X  
Sulphur (Sulfur) 3X

**PURPOSE**

Cuts, burns  
Itching skin  
Scrapes, scars  
Itchy dry skin  
Burning pain  
Chapped rough skin

These claims have not been reviewed by the Food and Drug Administration. They are based on traditional homeopathic practice.

The letters "HPUS" indicate that the components in this product are officially monographed in the Homoeopathic Pharmacopoeia of the United States.

**USES**

This homeopathic medicine is made from a combination of ingredients traditionally used to help:

- promote healing of minor cuts, scrapes, scars and burns
- soften itchy dry, rough or chapped skin.

**WARNINGS**

**For external use only.**

**Do not use** if film wrapper is broken or missing.

**When using this product**, avoid contact with eyes; if contact occurs, rinse abundantly with water to remove.

**Stop use and ask a doctor**

- if symptoms persist for more than 3 days or worsen
- if hypersensitivity and/or allergy occurs.

**Keep out of reach of children.** If ingested, get medical help or contact a Poison Control Center immediately.

## DIRECTIONS

- Clean affected area and apply a thin layer 3 times a day or as needed. May be covered with a sterile bandage.
- Children under 2 yrs: ask a doctor.

## OTHER INFORMATION

Store at room temperature (68 - 77°F).

## INACTIVE INGREDIENTS

Carbomer, cetareth-12, cetylalcohol, cetyl alcohol, cetyl palmitate, DMDM hydantoin, glycerin, glyceryl cocoate, glyceryl stearate, iodopropynyl butylcarbamate, isopropyl myristate, isopropyl palmitate, octyldodecanol, PEG-20 glyceryl stearate, PEG-100 stearate, purified water, sodium hydroxide, sorbitan stearate.

## LABEL



## KIDS RELIEF CALENDULA

calendula officinalis, echinacea angustifolia, hypericum perforatum, phytolacca decandra, cantharis, sulphur cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:60512-9204
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CALENDULA OFFICINALIS FLOWERING TOP (UNII: 18E7415PXQ) (CALENDULA OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)	CALENDULA OFFICINALIS FLOWERING TOP	1 [hp_X] in 50 g
ECHINACEA ANGUSTIFOLIA (UNII: VB06AV5US8) (ECHINACEA ANGUSTIFOLIA - UNII:VB06AV5US8)	ECHINACEA ANGUSTIFOLIA	1 [hp_X] in 50 g
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB) (HYPERICUM PERFORATUM - UNII:XK4IUX8MNB)	HYPERICUM PERFORATUM	3 [hp_X] in 50 g
PHYTOLACCA AMERICANA ROOT (UNII: 11E6V18VEG) (PHYTOLACCA AMERICANA ROOT - UNII:11E6V18VEG)	PHYTOLACCA AMERICANA ROOT	3 [hp_X] in 50 g
LYTTA VESICATORIA (UNII: 3Q034RO3BT) (LYTTA VESICATORIA - UNII:3Q034RO3BT)	LYTTA VESICATORIA	3 [hp_X] in 50 g
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	3 [hp_X] in 50 g

## Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMO POLYMER TYPE A (UNII: F68VH75CJC)	
CETEARETH-12 (UNII: 7V4MR24V5P)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL COCOATE (UNII: WVK1CT5994)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
PEG-20 GLYCERYL STEARATE (UNII: MJV0165YY8)	
PEG-100 STEARATE (UNII: YD01N1999R)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60512-9204-1	50 g in 1 JAR; Type 0: Not a Combination Product	11/07/2016	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		11/07/2016	

**Labeler** - HOMEOLAB USA INC (202032533)

## Establishment

Name	Address	ID/FEI	Business Operations
HOMEOLAB USA INC		202032533	manufacture(60512-9204)

Revised: 11/2016

HOMEOLAB USA INC