# CALENDULA OFF- calendula off gel Rxhomeo Private Limited d.b.a. Rxhomeo, 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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#### ACTIVE INGREDIENT

CALENDULA OFF GEL TINC HPUS

#### **USES**

Minor cuts, scrapes, burns, skin irritation and diaper rash

## **INDICATIONS**

Condition listed above or as directed by the physician

## **DOSAGE & ADMINISTRATION SECTION**

Apply a thin layer of Gel to the affected area, repeat 3 times a day or as needed.

## **WARNINGS**

This product is to be used for self-limiting conditions

If symptoms do not improve in 4 days, or worsen, discontinue use and seek assistance of health professional

As with any drug, if you are preganant, or nursing a baby, seek professional advice before taking this product

Keep this and all medication out of reach of children

Do not use if capseal is broken or missing. Close the cap tightly after use.

#### INACTIVE INGREDIENTS

ALOE VERA GEL

#### **STORAGE**

Store in a cool dark place

## **QUESTIONS OR COMMENTS**

www.Rxhomeo.com | 1.888.2796642 | info@rxhomeo.com

Rxhomeo, Inc 9415 Burnet Road, Suite 312, Austin, TX 78758









## **CALENDULA OFF**

calendula off gel

## **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:15631-2310

Route of Administration TOPICAL

# **Active Ingredient/Active Moiety**

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Ingredient Name	Basis of Strength	Strength
	CALENDULA OFFICINALIS	1 [hp_X]

OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)

FLOWERING TOP

## **Inactive Ingredients**

Ingredient Name	Strength
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ALOE VERA LEAF (UNII: ZY81Z83H0X)

#### **Packaging Marketing Start Date Marketing End Date** Item Code Package Description 1 NDC:15631-2310-0 1 in 1 CONTAINER 03/30/2016 50 g in 1 CONTAINER; Type 0: Not a Combination Product 2 NDC:15631-2310-1 1 in 1 CONTAINER 03/30/2016 100 g in 1 CONTAINER; Type 0: Not a Combination Product **3** NDC:15631-2310-2 1 in 1 CONTAINER 03/30/2016 200 g in 1 CONTAINER; Type 0: Not a Combination Product **4** NDC:15631-2310-3 1 in 1 CONTAINER 03/30/2016 500 g in 1 CONTAINER; Type 0: Not a Combination Product

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved homeopathic		03/30/2016		

# Labeler - Rxhomeo Private Limited d.b.a. Rxhomeo, Inc (650833994)

Establishment					
Name	Address	ID/FEI	Business Operations		
Rxhomeo Private Limited d.b.a. Rxhomeo, Inc		650833994	manufacture(15631-2310), label(15631-2310)		

Revised: 3/2016 Rxhomeo Private Limited d.b.a. Rxhomeo, Inc