

**CALMING ITCH AND IRRITATION- colloidal oatmeal lotion**  
**Better Planet Brands LLC**

*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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**Calming Itch & Irritation Lotion**

**Active Ingredients**

Active ingredients Purpose

Colloidal Oatmeal 2.0%..... Skin Protectant

**Purpose**

Purpose

Skin Protectant

**Uses**

**Uses**

\* Help prevent and temporarily protects chafed, chapped or cracked skin

**Warnings**

**Warnings** For external use only.

**When using the product** \* Do not get into eyes

**Stop use and ask a doctor if**

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\* Condition worsens \* Symptoms last more than 7 days or clear up and occur again within a few days

**Do not use on**

\* Deep or puncture wounds \* Animal bites \* Serious burns

**SAFETY TIP: Keep out of reach of children.**

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If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

Directions

\* Apply liberally or as needed. Do not use if quality seal is broken

**Other information**

## Other information

\* Remove quality seal. Do not use if quality seal is broken. Store at room temperature.

## Inactive Ingredients

Inactive Ingredients ALOE BARBADENSIS LEAF JUICE, CARTHAMUS TINCTORIUS (SAFFLOWER) SEED OIL, CETEARYL OLIVATE, COCOGLYCERIDES, GLYCERIN, GLYCERYL LAURATE, GLYCERYL STEARATE SE, HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL, HIPPOPHAE RHAMNOIDES (SEABUCKTHORN) SEED OIL, LAVANDULA ANGUSTIFOLIA (LAVENDER) OIL, LIMNANTHES ALBA (MEADOWFOAM) SEED OIL, OLEA EUROPAEA (OLIVE) FRUIT OIL, POTASSIUM SORBATE, SODIUM LEVULINATE, SORBITAN OLIVATE, SQUALANE, THEOBROMA CACAO (COCOA) SEED BUTTER, TOCOPHEROL, WATER/AQUA, XANTHAN GUM.

## Questions?

Questions? Call toll-free 877.902.2873

NDC 54136-322-81. 239 g (236.5 mL) Tube

**ACURE**<sup>®</sup>  
WELCOME TO SKIN WELLNESS™

**CALMING  
ITCH &  
IRRITATION  
LOTION**

**Lavender  
& colloidal oatmeal  
protect & soothe**

<b>Drug Facts</b>	
<b>Active Ingredient</b>	<b>Purpose</b>
Colloidal Oatmeal 2.0%	Skin Protectant
<b>Uses</b> ■ Helps prevent and temporarily protects chafed, chapped or cracked skin	
<b>Warnings</b> For external use only When using this product ■ Do not get into eyes Stop use and ask doctor if ■ Condition worsens ■ Symptoms last more than 7 days or clear up and occur again within a few days Do not use on ■ Deep or puncture wounds ■ Animal bites ■ Serious burns SAFETY TIP: Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> ■ Apply liberally or as needed. Do not use if quality seal is broken	
<b>Other information</b> Remove quality seal. Do not use if quality seal is broken.	
<b>Inactive ingredients</b> ALOE VERA BARBADENSIS LEAF JUICE, CARTHAMUS TINCTORIUS (SAFFLOWER) SEED OIL, CETEARYL OLIVATE, COCOGLYCERIDES, GLYCERIN, GLYCERYL LAURATE, GLYCERYL STEARATE SE, HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL, HIPPOPHAE RHAMNOIDES (SEABUCKTHORN) SEED OIL, LAVANDULA ANGUSTIFOLIA (LAVENDER) OIL, LIMNANTHES ALBA (MEADOWFOAM) SEED OIL, OLEA EUROPAEA (OLIVE) FRUIT OIL, POTASSIUM SORBATE, SODIUM LEVULINATE, SORBITAN OLIVATE, SQUALANE, THEOBROMA CACAO (COCOA) SEED BUTTER, TOCOPHEROL, WATER/AQUA, XANTHAN GUM.	
<b>Questions?</b> Call toll-free 877.902.2873	

We believe that skin wellness means helping your skin thrive with soothing hydration and botanical ingredients. Thrive on!

body lotion  
lotion pour le corps

**100% VEGAN. 0% PRETENTIOUS.**

Paraben free, Sulfate free,  
Mineral oil free, Petrolatum free,  
Silicone free, Cruelty free

**8 FL. OZ. (236.5 ml)**

MANUFACTURED FOR  
BETTER PLANET BRANDS, LLC  
1635 SE 17TH STREET, SUITE 107  
FORT LAUDERDALE, FL 33316 USA  
871302.2873 ACURE.COM  
MADE IN THE USA OF DOMESTIC &  
GLOBAL INGREDIENTS & COMPONENTS  
TUBE CONTAINS RECYCLED MATERIAL  
MANUFACTURED IN A FACILITY  
AUDITED FOR SOCIAL RESPONSIBILITY



## CALMING ITCH AND IRRITATION

colloidal oatmeal lotion

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54136-322
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OATMEAL (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y)	OATMEAL	2 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
SUNFLOWER OIL (UNII: 3W1JG795YI)	
WATER (UNII: 059QF0KO0R)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
MEADOWFOAM SEED OIL (UNII: 412ZHA4T4Y)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
COCOA BUTTER (UNII: 512OYT1CRR)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
COCO-GLYCERIDES (UNII: ISE9I7DNUG)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
HIPPOPHAE RHAMNOIDES SEED OIL (UNII: T53SBG6741)	

<b>OLIVE OIL</b> (UNII: 6UYK2W1W1E)	
<b>SAFFLOWER OIL</b> (UNII: 65UEH262IS)	
<b>GLYCERYL LAURATE</b> (UNII: Y98611C087)	
<b>SODIUM LEVULINATE</b> (UNII: VK44E1MQU8)	
<b>SQUALANE</b> (UNII: GW89575KF9)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54136-322-81	239 g in 1 TUBE; Type 0: Not a Combination Product	05/11/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	05/11/2020	

**Labeler** - Better Planet Brands LLC (960253719)

Revised: 5/2020

Better Planet Brands LLC