

DR. SAYMAN WONDER CREAM- colloidal oatmeal cream
Sheffield Pharmaceuticals 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.

Drug Facts

Active ingredient

Colloidal Oatmeal 5%

Purpose

Skin protectant

Uses

Temporarily protects and helps relieve minor skin irritation and itching due to:

- Eczema
- Rashes

Warnings

For external use only

Do not use on wounds or damaged skin or if you are allergic to the ingredients in the product

When using this product

- Avoid contact with eyes, if product gets into eyes, rinse thoroughly with water.
- Do not bandage tightly or use a heating pad

Stop use and ask a doctor if

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days

Keep out of reach of children.

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

Directions

- Apply to the affected area as needed
- Test a small area on your skin to check for any potential allergic reaction

Other information

store at room temperature 68° -77°F (20° -25°C)

Inactive Ingredients:

Water (purified), Glyceryl Stearate SE, Glycerin, Lanolin, Honey (Manuka), Polysorbate 80, Sodium Citrate, Tocopherol, Beeswax, Argania Spinosa (Argan) Kernel Oil, Cocos Nucifera

(Coconut) Oil, Persea Grattissima (Avocado) Oil, Cannabis Sativa Seed Oil, Salix Alba (Willow) Bark Extract, Butyrospermum Parkii (Shea) Butter, Aloe Barbadensis Leaf, Curcuma Longa (Turmeric) Root Extract, Carthamus Tinctorius (Safflower) Seed Oil, Glycyrrhiza Glabra (Licorice) Root Extract, Olea Europaea (Olive) Fruit Oil, Cholecalciferol (Vitamin D3), Zea Mays (Corn) Oil, Magnesium Carboxymethyl Beta-Glucan, Phenethyl Alcohol, Pentylene Glycol, Propanediol, Carbomer, Dehydroacetic Acid, Disodium EDTA, Citric Acid

Principal Display panel - Jar

Dr. Saymans Wonder Cream

Colloidal Oatmeal 5%

Helps prevent Dry and Itchy Skin

Net WT 6.0 oz (170g)



Clear Label



Principal Display panel- Carton

Dr. Sayman Wonder Cream

Collodial Oatmeal 5%

Helps prevent dry and Itchy Skin

Net Wt 6oz (170g)



DR. SAYMAN WONDER CREAM

colloidal oatmeal cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11527-348
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OATMEAL (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y)	OATMEAL	50 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
GLYCERIN (UNII: PDC6A3C0OX)	
LANOLIN (UNII: 7EV65EAW6H)	
HONEY (UNII: Y9H1V576FH)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

TOCOPHEROL (UNII: R0ZB2556P8)
YELLOW WAX (UNII: 2ZA36H0S2V)
ARGAN OIL (UNII: 4V59G5UW9X)
COCONUT OIL (UNII: Q9L0O73W7L)
AVOCADO OIL (UNII: 6VNO72PFC1)
CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S)
SALIX ALBA BARK (UNII: 205MXS71H7)
SHEA BUTTER (UNII: K49155WL9Y)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CURCUMA LONGA WHOLE (UNII: W5488JUO8U)
SAFFLOWER OIL (UNII: 65UEH262IS)
LICORICE (UNII: 61ZBX54883)
OLIVE OIL (UNII: 6UYK2W1W1E)
CHOLECALCIFEROL (UNII: 1C6V77QF41)
CORN OIL (UNII: 8470G57WFM)
SACCHAROMYCES CEREVISIAE (UNII: 978D8U419H)
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)
PENTYLENE GLYCOL (UNII: 50C1307PZG)
PROPANEDIOL (UNII: 5965N8W85T)
CARBOMER 940 (UNII: 4Q93RCW27E)
DEHYDROACETIC ACID (UNII: 2KAG279R6R)
EDETATE DISODIUM (UNII: 7FLD91C86K)
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11527-348-60	1 in 1 CARTON	01/25/2019	
1		170 g in 1 JAR; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	01/25/2019	

Labeler - Sheffield Pharmaceuticals LLC (151177797)

Establishment			
Name	Address	ID/FEI	Business Operations
Sheffield Pharmaceuticals LLC		151177797	MANUFACTURE(11527-348)