

**RE/COVER KIT- colloidal oatmeal
KAO USA**

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click [here](#).

Re/Cover

Drug Facts

Active ingredient

Colloidal oatmeal 1%

Purpose

Skin protectant

Uses

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

Warnings

For external use only.

When using this product, do not get into eyes.

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 affected areas of skin as illustrated in the USAGE INSTRUCTIONS.

Other information

store at room temperature

Inactive ingredients

water, glycerin, cetearyl alcohol, petrolatum, stearic acid, C12-15 alkyl benzoate, dimethicone, aesculus hippocastanum (horse chestnut) seed extract, laureth-3, hydroxyacetophenone, cetareth-20, allantoin, arginine, sodium hydroxide, carbomer, panthenol, tetrasodium glutamate diacetate, phenoxyethanol

Questions or comments?






1-800-309-1638

Moisture Patch Instructions

USAGE INSTRUCTIONS

For best results, apply patch on clean skin in the morning and a new patch at night, for 7 days. Remove previous patch before applying a new one.

APPLICATION OF PATCH

-  Carefully open pouch to remove patch. Set aside.
-  Dispense 1 pump of serum. Spread across affected area. Area should be slightly larger than patch. Do not fully rub in.
-  Take patch and gently press white side down over the serum. Blue side should be facing up.
-  Pat blue side down with fingertips. Gently peel blue backing off patch.
-  Add 1 pump of serum on patch. Gently rub in over entire patch to help patch adhere. Wait 5-10 minutes. Patch will begin to disappear on skin.

REMOVAL OF PATCH

Gently peel patch back starting at edges. If edge is not visible, wet area with water and gently rub skin to remove patch.

*patch is not waterproof
visit www.recover skincare.com for video application*

MOISTURE PATCH INGREDIENTS

Polyvinyl butyral, PEG-60 hydrogenated castor oil, butylene glycol

re/cover™

ECZEMA RELIEF SYSTEM

Fast-acting system quickly relieves the disruption and discomfort of eczema with a soothing serum and invisible protective moisture patch to help recover healthy-looking skin

+CALMING ECZEMA SERUM

COLLOIDAL OATMEAL SKIN PROTECTANT

+MOISTURE PATCHES

- Serum helps to shorten eczema flare ups and relieve the itch
- Dermatologist Tested
- Steroid Free

7 DAY SYSTEM

14 MOISTURE PATCHES

0.30 FL OZ (9 mL) CALMING ECZEMA SERUM

For additional information:

www.recover skincare.com

or 1-800-309-1638

RE/COVER is a trademark of Kao Corp.

Distributed by Kao USA Inc.

Cincinnati, OH 45214

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Patch: Made in Japan.

Serum: Made in USA of US & Imported Ingredients

re/cover™
ECZEMA RELIEF SYSTEM

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Gently peel patch back starting at edges. If edge is not visible, wet area with water and gently rub side to remove patch.

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Drug Facts - Calming Eczema Serum

Active ingredients
Colloidal Oatmeal 1% Skin Protectant

Purpose
Temporarily protects and helps relieve minor skin irritation and itching due to eczema.

Warnings
For external use only.
When using this product, do not get into eyes.
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 affected areas of skin as illustrated in the USAGE INSTRUCTIONS.

Other information store at room temperature

Inactive ingredients Water, Glycerin, Carbonyl Amide, Hydroxurea, Stearic Acid, C12-15 Alkyl Benzoate, Dimethicone, Aesculus Hippocastanum (Horse Chestnut) Seed Extract, Laureth-3, Hydroxyacetophenone, Ceteareth-20, Alcobon, Arginine, Sodium Hydroxide, Carbonic, Panthenol, Tetrasodium Glutamate Diacetate, Phenoxyethanol.

Questions or comments? 1-800-309-1638

MOISTURE PATCH INGREDIENTS:
POLYETHYLENE TEREPHTHALATE, PEG-60 HYDROGENATED CASTOR OIL, BUTYLENE GLYCOL.

For additional information:
www.recover skincare.com
or 1-800-309-1638
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Distributed by Kao USA Inc., Cincinnati, OH 45214
Patch: Made in Japan.
Serum: Made in USA of US & Imported Ingredients.

re/cover™
ECZEMA RELIEF SYSTEM

Fast-acting system quickly relieves the disruption and discomfort of eczema with a soothing serum and invisible protective moisture patch to help recover healthy-looking skin

+ CALMING ECZEMA SERUM
COLLOIDAL OATMEAL SKIN PROTECTANT

+ MOISTURE PATCHES

- Serum helps to shorten eczema flare ups and relieve the itch
- Dermatologist Tested
- Steroid Free

7 DAY SYSTEM
14 MOISTURE PATCHES
0.30 FL OZ (9 mL) CALMING ECZEMA SERUM

Non-Steroid Relief
Fragrance Free Serum
Gentle & Non-Irritating
Dye Free Serum
Paraben Free
Invisible Protection
Safe for those with Sensitive Skin

RE/COVER KIT
colloidal oatmeal kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10596-901
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10596-901-03	1 in 1 KIT; Type 0: Not a Combination Product	08/21/2023	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	0 BOTTLE, WITH APPLICATOR	1 mL

Part 1 of 1

RE/COVER SERUM

colloidal oatmeal emulsion

Product Information

Item Code (Source)	NDC:10596-902
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OATMEAL (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y)	OATMEAL	1 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
PETROLATUM (UNII: 4T6H12BN9U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
HORSE CHESTNUT (UNII: 3C18L6RJAZ)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
ARGININE (UNII: 94ZLA3W45F)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
LAURETH-3 (UNII: F32E4CB0UJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
ALLANTOIN (UNII: 344S277G0Z)	

CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
PANTHENOL (UNII: WW9CM0O67Z)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		9 mL in 1 BOTTLE, WTH APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M016	08/21/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/21/2023	

Labeler - KAO USA (004251617)

Revised: 8/2023

KAO USA