

FIRST AID BEAUTY FAB ULTRA REPAIR SKIN PROTECTANT PINK GRAPEFRUIT- colloidal oatmeal cream

The Procter & Gamble Manufacturing Company

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.

First Aid Beauty FAB Ultra Repair Cream Skin Protectant Pink Grapefruit

Drug Facts

Active ingredients

Colloidal Oatmeal 0.5%

Purpose

Skin Protectant

Uses

- Temporarily protects and helps relieve minor skin irritation and itching due to eczema, rashes, poison ivy, oak or sumac, insect bites

Warnings

For external use only.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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

Directions

Apply as needed

Water, stearic acid, glycerin, c12-15 alkyl benzoate, caprylic/capric triglyceride, glyceryl stearate, glyceryl stearate SE, cetearyl alcohol, butyrospermum parkii (shea) butter, dimethicone, squalene, phenoxyethanol, caprylyl glycol, xanthan gum, citrus paradisi, citrus reticulata (tangerine) peel oil, Orange terpenes, allantoin, sodium hydroxide, tetrasodium EDTA, chrysanthemum parthenium (feverfew) extract, camellia sinensis leaf extract, glycyrrhiza glabra (licorice) root extract, ceramide NP

Questions:

888-FAB-3063

MADE IN USA

FIRST AID BEAUTY LTD

NEWTON, MA 02458

WWW.FIRSTAIDBEAUTY.COM

PRINCIPAL DISPLAY PANEL - 14.0 oz (396.8 g)

First Aid Beauty

FAB

Ultra Repair® Cream

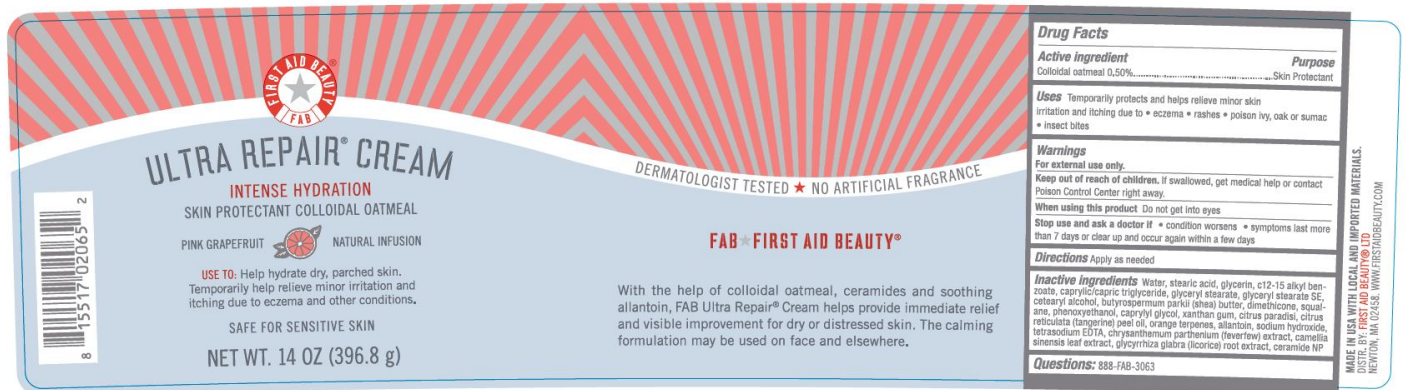
Intense Hydration

Skin Protectant Colloidal Oatmeal

Pink Grapefruit Natural Infusion

First Aid Beauty®

Net Wt. 14.0 oz (396.8 g)



Drug Facts

Active ingredient	Purpose
Colloidal oatmeal 0.50%	Skin Protectant

Uses Temporarily protects and helps relieve minor skin irritation and itching due to • eczema • rashes • poison ivy, oak or sumac • insect bites

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Directions Apply as needed

Inactive ingredients Water, stearic acid, glycerin, c12-15 alkyl benzoate, caprylic/capric triglyceride, glyceryl stearate, glyceryl stearate SE, cetearyl alcohol, butyrospermum parkii (shea) butter, dimethicone, squaleane, phenoxethanol, caprylyl glycol, xanthan gum, citrus paradisi, citrus reticulata (tangerine) peel oil, orange terpenes, allantoin, sodium hydroxide, tetrasodium EDTA, chrysanthemum parviflorum (feverfew) extract, camellia sinensis leaf extract, glycyrrhiza glabra (licorice) root extract, ceramide NP

Questions: 888-FAB-3063

MADE IN USA WITH LOCAL AND IMPORTED MATERIALS.
DISTR. BY: FIRST AID BEAUTY LTD
NEWTON, MA 02458 WWW.FIRSTAIDBEAUTY.COM

FIRST AID BEAUTY FAB ULTRA REPAIR SKIN PROTECTANT PINK GRAPEFRUIT

colloidal oatmeal cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69423-567
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OATMEAL (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y)	OATMEAL	0.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
GRAPEFRUIT (UNII: O82C39RR8C)	
TANACETUM PARTHENIUM WHOLE (UNII: 6GE7Z0761K)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
SQUALANE (UNII: GW89575KF9)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SHEA BUTTER (UNII: K49155WL9Y)	
GLICYRRHIZA GLABRA (UNII: 2788Z9758H)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALLANTOIN (UNII: 344S277G0Z)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
MANDARIN OIL (UNII: NJO720F72R)	
CERAMIDE NP (UNII: 4370DF050B)	
ORANGE TERPENES (UNII: 9J3RG7FX7S)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69423-567-57	56.7 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2021	09/10/2022
2	NDC:69423-567-56	56.7 g in 1 JAR; Type 0: Not a Combination Product	01/01/2021	09/10/2022
3	NDC:69423-567-17	170.1 g in 1 JAR; Type 0: Not a Combination Product	01/01/2021	09/10/2022
4	NDC:69423-567-23	226 g in 1 JAR; Type 0: Not a Combination Product	01/01/2021	09/10/2022
5	NDC:69423-567-34	340.2 g in 1 JAR; Type 0: Not a Combination Product	01/01/2021	
6	NDC:69423-567-39	396.8 g in 1 JAR; Type 0: Not a Combination Product	01/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M016	01/01/2021	

Revised: 1/2023

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