

**FIRST AID BEAUTY FAB ULTRA REPAIR INTENSE HYDRATION SKIN
PROTECTANT CRANBERRY POMEGRANATE- 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 Cranberry
Pomegranate**

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, allantoin, sodium hydroxide, tetrasodium EDTA, chrysanthemum parthenium (feverfew) extract, triethyl citrate, camellia sinensis leaf extract, glycyrrhiza glabra (licorice) root extract, cinnamomum camphora linalooliferum wood extract, citrus limon (lemon) peel extract, punica granatum seed extract, rubus idaeus (raspberry) fruit extract, vaccinium macrocarpon (cranberry) seed oil, ceramide NP, ananas sativus (pineapple) fruit extract,

citrus paradisi (grapefruit) peel extract, cucumis melo (melon) fruit extract, passiflora incarnata fruit extract, pimpinella anisum (anise) fruit extract, pyrus malus (apple) fruit extract, rosa damascene flower extract, Theobroma cacao (cocoa) extract, tsuga canadensis oil, vaccinium macrocarpon (cranberry) fruit extract, vanilla planifolia fruit extract

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

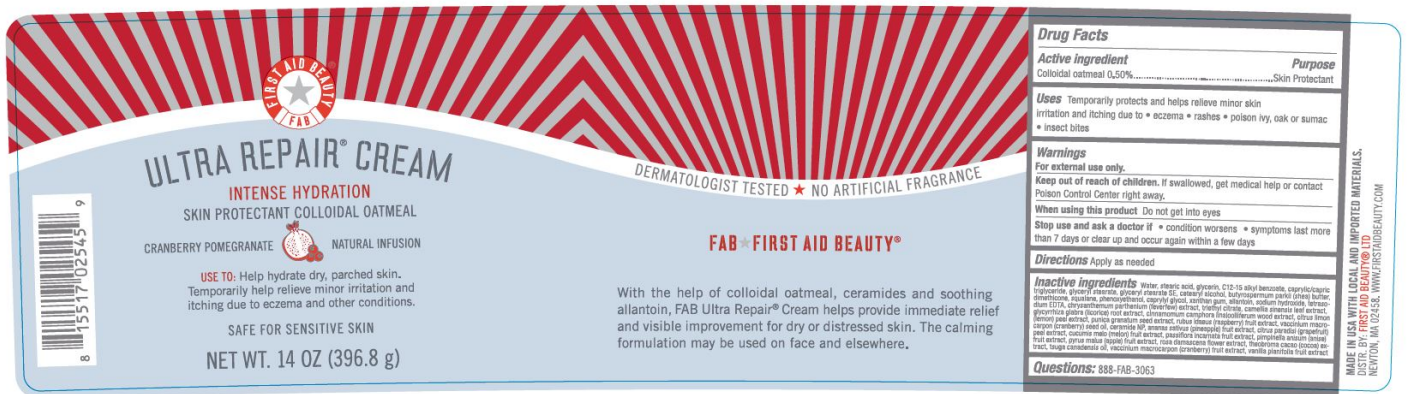
Ultra Repair® Cream

Intense Hydration

Skin Protectant Colloidal Oatmeal

Cranberry Pomegranate Natural Infusion

Net Wt. 14.0 oz (396.8 g)



FIRST AID BEAUTY FAB ULTRA REPAIR INTENSE HYDRATION SKIN PROTECTANT CRANBERRY POMEGRANATE

colloidal oatmeal cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69423-565
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
TSUGA CANADENSIS LEAF OIL (UNII: Q1S51LGQ0G)	
MUSKMELON (UNII: ZV095H5633)	
PASSIFLORA INCARNATA FRUIT (UNII: SF206I8G4P)	
TANACETUM PARTHENIUM WHOLE (UNII: 6GE7Z0761K)	
MENTHA PIPERITA LEAF (UNII: A389O33LX6)	
APPLE (UNII: B423VGH5S9)	
CRANBERRY SEED OIL (UNII: 73KDS3BW5E)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
SQUALANE (UNII: GW89575KF9)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EDETATE SODIUM (UNII: MP1J8420LU)	
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)	
GLYCYRRHIZA 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)	
PINEAPPLE (UNII: 2A88Z0081O)	
CERAMIDE NP (UNII: 4370DF050B)	
VANILLA BEAN (UNII: Q74T35078H)	
RASPBERRY (UNII: 4N14V5R27W)	
LEMON PEEL (UNII: 72O054U628)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
CRANBERRY (UNII: 0MVO31Q3QS)	
GRAPEFRUIT PEEL (UNII: 3582N05Q44)	
ANISE (UNII: 21C2F5E8RE)	
ROSA DAMASCENA FLOWER (UNII: JWB78P295A)	
COCOA (UNII: D9108TZ9KG)	
POMEGRANATE SEED (UNII: 7294Z34NS7)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69423-565-39	396.8 g in 1 JAR; Type 0: Not a Combination Product	01/01/2023	
2	NDC:69423-565-56	56 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M016	01/01/2023	

Labeler - The Procter & Gamble Manufacturing Company (004238200)

Revised: 2/2023

The Procter & Gamble Manufacturing Company