

BERRY POWERFUL LIP CARE- dimethicone jelly
JAFRA COSMETICS INTERNATIONAL

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.

Royal Jelly Berry Powerful Lip Care

Active ingredient Purpose

Dimethicone 2.0% Skin protectant

Uses

Helps prevent and temporarily chapped or cracked lips

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

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

Warnings

For external use only

When using this product do not get into eyes

Do not use deep on

- Deep puncture wounds
- Animal Bites
- Serious burns

Directions

Apply as needed.

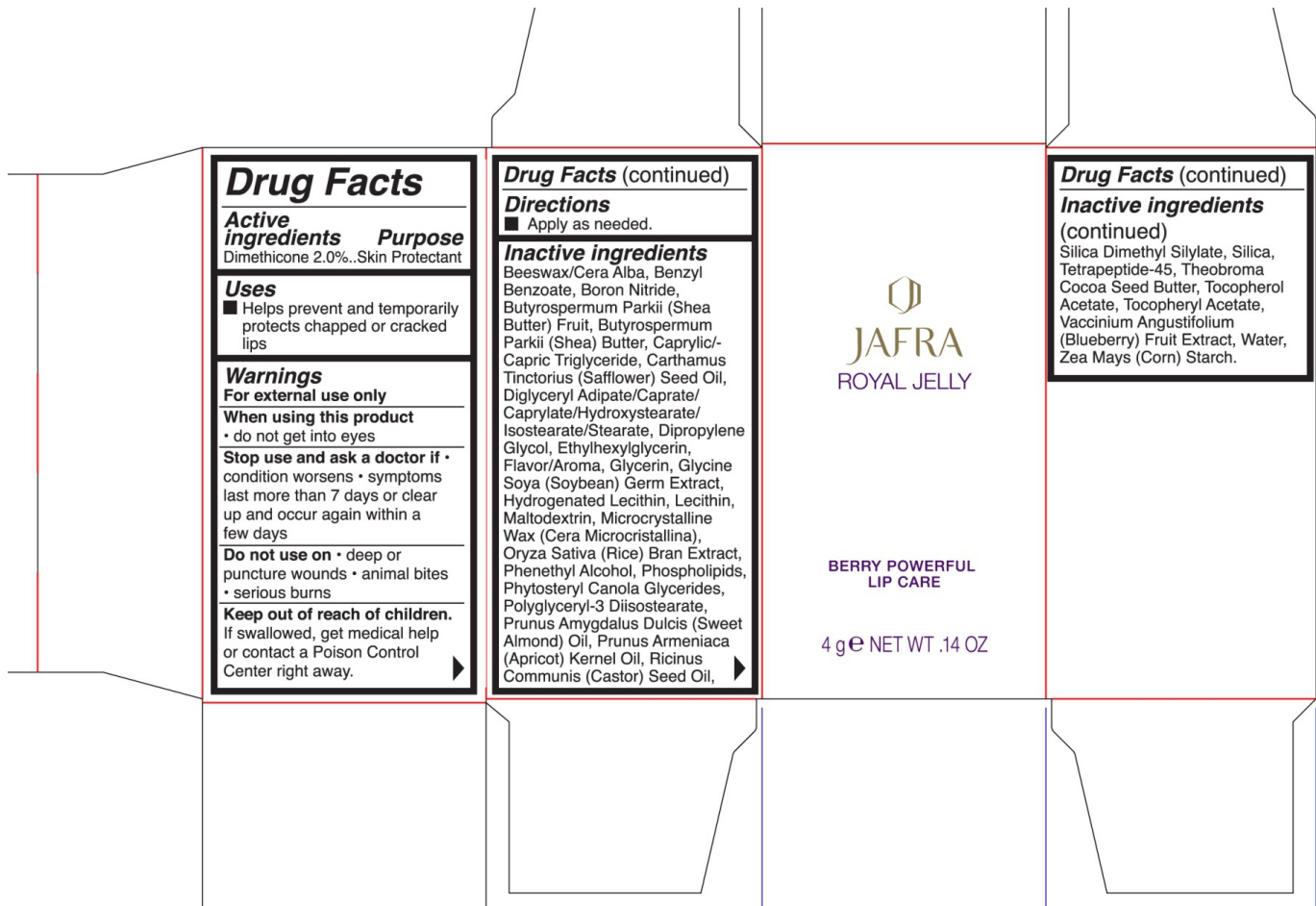
Inactive ingredients

Beeswax/Cera Alba, Benzyl Benzoate, Boron Nitride, Butyrospermum Parkii (Shea) Butter, Caprylic/Capric Triglyceride, Carthamus Tinctorius (Safflower) Seed Oil, Diglyceryl Adipate/Caprate/Caprylate/Hydroxystearate/Isostearate/Stearate, Dipropylene Glycol, Ethylhexylglycerin, Flavor/Aroma, Glycerin, Glycine Soya (Soybean) Germ Extract, Hydrogenated Lecithin, Lecithin, Maltodextrin, Microcrystalline Wax (Cera Microcrystallina), Oryza Sativa (Rice) Bran Extract, Phenethyl Alcohol, Phospholipids, Phytosteryl Canola Glycerides, Polyglyceryl-3 Diisostearate, Prunus Amygdalus dulcis (sweet Almond) Oil, Prunus Armeniaca (Apricot) Kernel Oil, Ricinus Communis (castor) seed Oil, Silica Dimethyl Silylate, Silica, Terapeptide-45, Theobroma Cocoa Seed Butter, Tocopherol Acetate, Vaccinium Angustifolium (Blueberry) Fruit Extract, Water, Zea Mays (Corn) Starch.

Jafra Royal Jelly

Berry Powerful Lip Care

4 g NET WT .14 oz



BERRY POWERFUL LIP CARE			
dimethicone jelly			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68828-278
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)		DIMETHICONE	2 g in 100 g
Inactive Ingredients			
Ingredient Name			Strength
BENZYL BENZOATE (UNII: N863NB338G)			
BORON NITRIDE (UNII: 2U4T60A6YD)			
SHEA BUTTER (UNII: K49155WL9Y)			
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)			
SAFFLOWER OIL (UNII: 65UEH262IS)			
DIPROPYLENE GLYCOL (UNII: E107L85C40)			
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)			
GLYCERIN (UNII: PDC6A3C0OX)			

SOYBEAN GERM (UNII: JBW2VHD14M)
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
MALTO DEXTRIN (UNII: 7CVR7L4A2D)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
RICE BRAN (UNII: R60QEP13IC)
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
ALMOND OIL (UNII: 66YXD4DKO9)
APRICOT KERNEL OIL (UNII: 54JB35T06A)
CASTOR OIL (UNII: D5340Y2I9G)
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
COCOA BUTTER (UNII: 512OYT1CRR)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
LOWBUSH BLUEBERRY (UNII: G90PX41VP0)
WATER (UNII: 059QF0KO0R)
STARCH, CORN (UNII: O8232NY3SJ)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68828-278-02	1 in 1 CARTON	10/13/2017	
1	NDC:68828-278-01	4 g in 1 TUBE; 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	10/13/2017	

Labeler - JAFRA COSMETICS INTERNATIONAL (041676479)

Establishment

Name	Address	ID/FEI	Business Operations
Jafra Manufacturing, S.A. de C.V.		814732061	manufacture(68828-278)

Revised: 6/2020

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