

OXY STEM M- dimethicone cream
ULAB

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.

ACTIVE INGREDIENT

Active ingredients: DIMETHICONE 14.12%

INACTIVE INGREDIENT

Inactive ingredients: Aqua (WATER), Glycerin, Glyceryl Stearate SE, Propylene Glycol, Water (aqua), Cetyl Alcohol, Hydrolyzed Pea, Pentylene Glycol, Glycerin, Carbomer, Triethanolamine, Fructose, Urea, Citric Acid, Phenoxyethanol, Ethylhexylglycerin, Sodium Hydroxide, Glycoproteins, Glutamic Acid, Maltose, Sodium PCA, Sodium Chloride, Sodium Lactate, Trehalose, Allantoin, Valine, Threonine, Sodium Hyaluronate, Glucose

PURPOSE

Purpose: Long-lasting moisturizing and skin smoothing

WARNINGS

Warnings: For external use only Avoid contact with eyes. Discontinue use if signs of irritation or rashes appear.

KEEP OUT OF REACH OF CHILDREN

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INDICATIONS & USAGE

Indications & Usage: Apply morning and night

DOSAGE & ADMINISTRATION

Dosage & Administration: Apply morning and night on clean face and neck after Oxy-Stem M Serum

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Drug Facts

Active ingredients	Purpose
DIMETHICONE 14.12%	Long-lasting moisturizing and skin smoothing

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Manufactured by ULAB Switzerland AG



OXY-STEM M
Cream

Energy-boosting and lifting cream.
Ensure long-lasting moisturizing and skin smoothing.
Provide brightening and tightening effects.
Enhance the youthful, glowing complexion.

e 50ml / 1.69 fl.oz.

 Made in Switzerland
ULAB Switzerland AG
 Bahnhofstrasse 3, CH-8808 Pfäffikon Switzerland
 www.ulabswiss.com



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OXY STEM M

dimethicone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71276-080
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	7.06 g in 50 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
Glycerin (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71276-080-02	1 in 1 CARTON	03/02/2017	
1	NDC:71276-080-01	50 mL in 1 BOTTLE, PUMP; 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	03/02/2017	

Labeler - ULAB (688976692)**Registrant** - ULAB (688976692)**Establishment**

Name	Address	ID/FEI	Business Operations
ULAB		688976692	relabel(71276-080)

Establishment

Name	Address	ID/FEI	Business Operations
U-LAB Switzerland AG		485958743	manufacture(71276-080)

Revised: 3/2017

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