

EROS SILICONE GLIDE AND CARE WOMAN- dimethicone gel
MEGASOL COSMETIC GMBH

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

DIMETHICONE 30%

PURPOSE

SKIN PROTECTANT

USES

- HELPS LUBRICATING IN BODY MASSAGE

WARNING:

- FOR EXTERNAL USE ONLY
- KEEP OUT OF REACH OF CHILDREN
- STOP USE AND ASK A DOCTOR IF RASH OR IRRITATION DEVELOPS AND LASTS.

DIRECTIONS FOR USE:

- APPLY AS NEEDED
- OPEN THE CAP, SQUEEZE TUBE TO OBTAIN DESIRED AMOUNT OF LUBRICANT. MAY BE APPLIED DIRECTLY ONTO CONDOMS. REAPPLY AS NEEDED. CLOSE CAP AFTER USE.
- RINSE WITH WATER TO REMOVE.

INACTIVE INGREDIENTS: DIMETHICONOL, CYCLOMETHICONE.

Drug Facts**Active Ingredients**

Dimethicone 30%

Purpose

Skin protectant

Uses:

- Helps lubricating in body massage
- Helps lubricating in sex intercourse

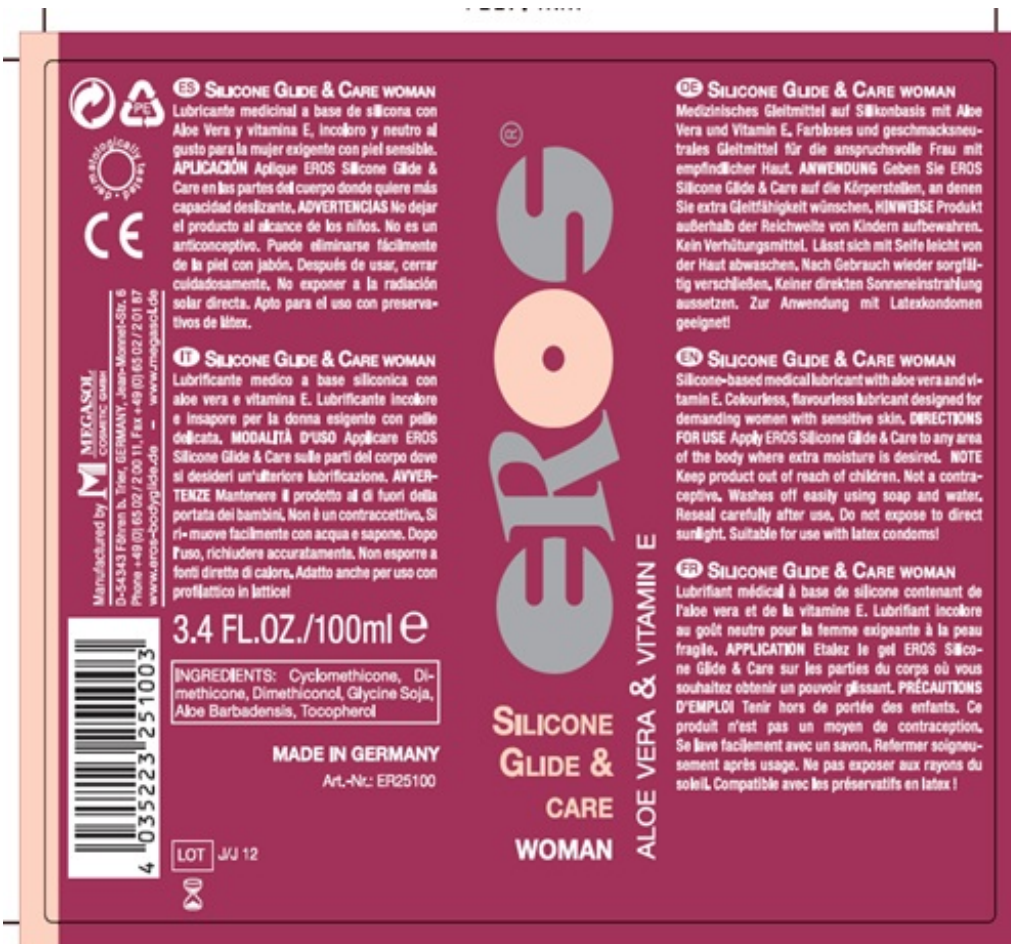
Warning:

- For external use only
- Stop use and ask a doctor if rash or irritation develops and lasts.
- Keep out of reach of children

Directions for use:

- Apply as needed
- Open the cap, squeeze tube to obtain desired amount of lubricant. May be applied directly onto condoms. Reapply as needed. Close cap after use.
- Rinse with water to remove.

Inactive Ingredients: Cyclomethicone, dimethiconol, glycine soja, aloe barbadensis, tocopherol.



EROS SILICONE GLIDE AND CARE WOMAN

dimethicone gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53389-251
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	30 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONOL (100000 CST) (UNII: OSA9UP217S)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
SOYBEAN OIL (UNII: 241ATL177A)	
ALOE VERA WHOLE (UNII: KIZ4X2EHYX)	
TOCOPHEROL (UNII: R0ZB2556P8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53389-251-14	100 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	10/01/2012	

Labeler - MEGASOL COSMETIC GMBH (344152855)**Establishment**

Name	Address	ID/FEI	Business Operations
MEGASOL COSMETIC GMBH		344152855	manufacture(53389-251)

Revised: 12/2012

MEGASOL COSMETIC GMBH