

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

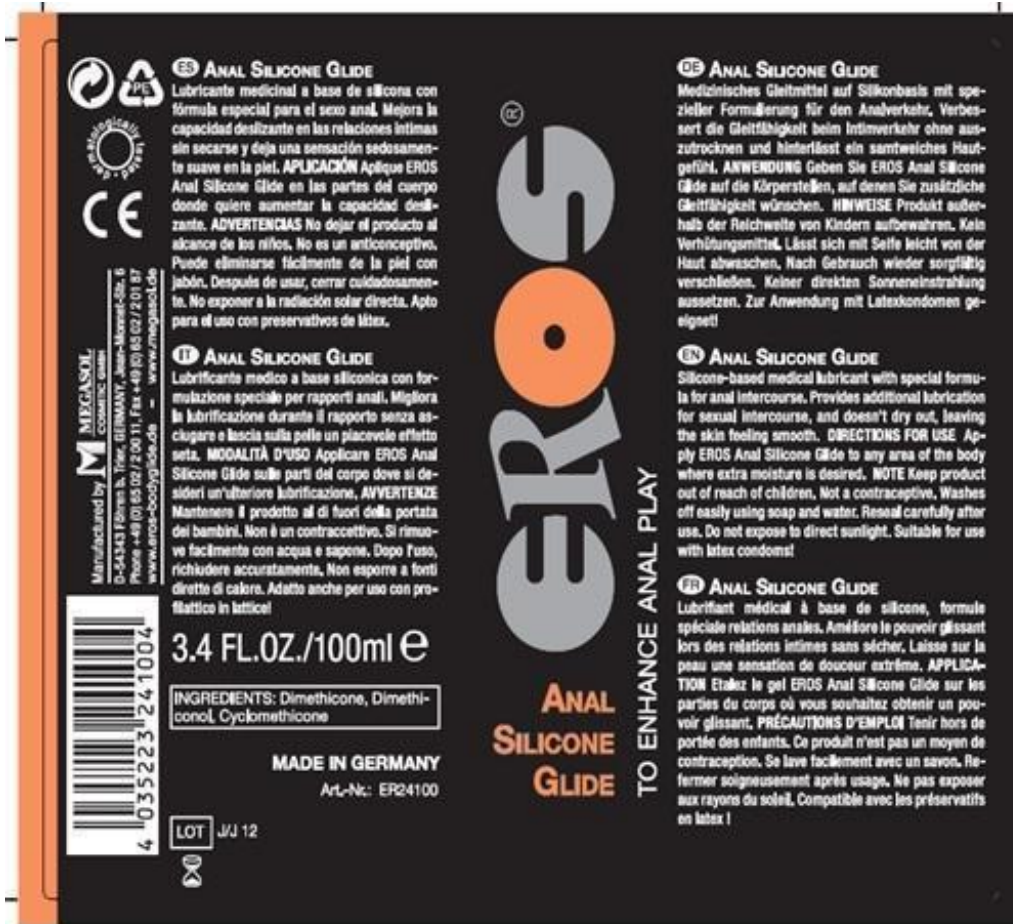
Warning:

- 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: Dimethiconol, cyclomethicone.



EROS SILICONE GLIDE AND CARE WOMAN

dimethicone gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:53389-100 |
| 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) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:53389-100-13 | 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(53389-100) |

Revised: 1/2013

MEGASOL COSMETIC GMBH