# EROS BODYGLIDE SUPER CONCENTRATED- 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.

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ACTIVE INGREDIENT

**DIMETHICONE 30%** 

**PURPOSE** 

SKIN PROTECTANT

#### **USES**

- HELPS LUBRICATING IN BODY MASSAGE
- HELPS LUBRICATING IN SEX INTERCOURSE

#### 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.

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.



3.4 FL.0Z./100 ml C

INGREDIENTS: Dimethicone, Dimethicone, Cyclomethicone

MADE IN GERMANY

Art.-Nr.: ER10100

LOT J/J 12



SUPER CONCENTRATED LUBRICANT

BODYGLIDE SUPER CONCENTRATED
LUBRICANT Medizinisches Gleitmittel auf Sili-

Bodyglide Super Concentrated LUBRICANT Silicone-based medical jubricant with unique formula – time-tested 100% EROS premium

BODYGLIDE SUPER CONCENTRATED RICANT Lubrifiant médical à base de silicone. de spéciale, silicone de qualité exceptionnel-

## EROS BODYGLIDE SUPER CONCENTRATED

dimethicone gel

Product Information				
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:53389-035	
Route of Administration	TOPICAL	DEA Schedule		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DIMETHICO NE (DIMETHICO NE)	DIMETHICONE	30 g in 100 mL	

Inactive Ingredients	
Ingredient Name	Strength
DIMETHICONOL (100000 CST)	
CYCLOMETHICONE 5	

## **Packaging**

# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:53389-035-14	100 mL in 1 TUBE			
Marketing Information				
Marketing Category	Application Number or Monogra	aph Citation Marketing Sta	rt 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(53389-035)	

Revised: 11/2012 MEGASOL COSMETIC GMBH