

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.

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.

| Drug Facts | |
|---|-----------------|
| Active Ingredients | Purpose |
| Dimethicone 30% | Skin protectant |
| Uses: | |
| <ul style="list-style-type: none">• Helps lubricating in body massage• Helps lubricating in sex intercourse | |
| Warning: | |
| <ul style="list-style-type: none">• 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: | |
| <ul style="list-style-type: none">• 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. | |

ES BODYGLIDE SUPER CONCENTRATED LUBRICANT Lubrificante medicinal a base de silicona con una fórmula única y su eficaz calidad superior de silicona 100% EROS. ¡Garantiza puro placer deslizante y una capacidad deslizante extremadamente duradera sin secarse! **APLICACIÓN** Aplique EROS Bodyglide Super Concentrated Lubricant en las partes del cuerpo donde quiere aumentar la capacidad deslizante. **ADVERTENCIAS** No dejar el producto al alcance de los niños. No es un anticonceptivo. Puede eliminarse fácilmente de la piel con jabón. Después de usar, cerrar cuidadosamente. No exponer a la radiación solar directa. ¡Apto para el uso con preservativos de látex!

IT BODYGLIDE SUPER CONCENTRATED LUBRICANT Lubrificante medico a base siliconica con esclusiva e provata formula 100% di qualità EROS Premium al silicone, garantisce una perfetta scorrevolezza per piacevolissimi momenti di Intimità e una lubrificazione estremamente durevole senza asciugare! **MODALITÀ D'USO** Applicare EROS Bodyglide Super Concentrated Lubricant sulle parti del corpo dove si desidera un'ulteriore lubrificazione. **AVVERTENZE** mantenere il prodotto al di fuori della portata dei bambini. Non è un contraccettivo. Si rimuove facilmente con acqua e sapone. Dopo l'uso, richiudere accuratamente. Non esporre a fonti dirette di calore. Adatto anche per uso con profilattico in lattice!

DE BODYGLIDE SUPER CONCENTRATED LUBRICANT Medizinisches Gleitmittel auf Silikonbasis mit einzigartiger Formulierung in der bewährten 100 % EROS Premium-Silikonqualität. Garantiert puren Gleitgenuss und extrem lang anhaltende Gleitfähigkeit ohne auszutrocknen! **ANWENDUNG** Geben Sie EROS Bodyglide Super Concentrated Lubricant auf Ihre Körperstellen, an denen Sie extra Gleitfähigkeit wünschen. **HINWEISE** Produkt außerhalb der Reichweite von Kindern aufbewahren. Kein Verhütungsmittel. Lässt sich mit Seife leicht von der Haut abwaschen. Nach Gebrauch wieder sorgfältig verschließen. Keiner direkten Sonneneinstrahlung aussetzen. Zur Anwendung mit Latexkondomen geeignet!

EN BODYGLIDE SUPER CONCENTRATED LUBRICANT Silicone-based medical lubricant with unique formula – time-tested 100% EROS premium silicone quality. Pure gliding pleasure guaranteed. Extremely long-lasting glide properties, without drying out! **DIRECTIONS FOR USE** Apply EROS Bodyglide Super Concentrated Lubricant to any area of the body where extra moisture is desired. **NOTE** Keep product out of reach of children. Not a contraceptive. Washes off easily using soap and water. Reseal carefully after use. Do not expose to direct sunlight. Suitable for use with latex condoms!

FR BODYGLIDE SUPER CONCENTRATED LUBRICANT Lubrifiant médical à base de silicone. Formule spéciale, silicone de qualité exceptionnelle 100% EROS. Garantit le plaisir le plus pur et un pouvoir glissant de très longue durée sans sécher. **APPLICATION** Etalez le gel EROS Bodyglide Super Concentrated Lubricant sur les parties du corps où vous souhaitez obtenir un pouvoir glissant. **PRÉCAUTIONS D'EMPLOI** Tenir hors de portée des enfants. Ce produit n'est pas un moyen de contraception. Se lave facilement avec un savon. Refermer soigneusement après usage. Ne pas exposer aux rayons du soleil. Compatible avec les préservatifs en latex !

EROS
BODYGLIDE
SUPER CONCENTRATED LUBRICANT

3.4 FL.OZ./100 ml e
INGREDIENTS: Dimethicone, Dimethiconol, Cyclomethicone
MADE IN GERMANY
Art.-Nr.: ER10100
LOT JJ 12

Manufactured by MEGASOL cosmetics GmbH
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EROS BODYGLIDE SUPER CONCENTRATED

dimethicone gel

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:53389-035 |
| 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:53389-035-14 | 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(53389-035) |

Revised: 11/2012

MEGASOL COSMETIC GMBH