

**EROS ANAL SILICONE - 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

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.

<b>Drug Facts</b>	
<b>Active Ingredients</b> Dimethicone 30%	<b>Purpose</b> Skin Protectant
<b>Uses:</b> <ul style="list-style-type: none"><li>• Helps lubricating in body massage</li></ul>	
<b>Warning:</b> <ul style="list-style-type: none"><li>• For external use only</li><li>• Stop use and ask a doctor if rash or irritation develops and lasts.</li><li>• Keep out of reach of children</li></ul>	
<b>Directions for use:</b> <ul style="list-style-type: none"><li>• Apply as needed</li><li>• Open the cap, squeeze tube to obtain desired amount of lubricant. May be applied directly onto condoms. Reapply as needed. Close cap after use.</li><li>• Rinse with water to remove.</li></ul>	
Inactive Ingredients: Dimethiconol, cyclomethicone.	



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**IT** EROS ANAL è un lubrificante medicinale su base di Silicone da applicare in combinazione con preservativi in lattice. Sicurezza del preservativo in lattice, migliora la lubrificazione durante il rapporto, ad alto rendimento, rilascia su la pelle un sentimento di seta, testato da un punto di vista dermatologico in merito a tolleranza su pelle e mucose, ne ogli o grassi, incolore e inodore, sapore neutro, senza Konservazinati, è specialmente indicato per l'utilizzo Anale. **Utilizzo:** applicate tutte le volte che lo desiderate quanto. EROS ANAL volete su quelle parti del corpo su cui desiderate un'idratazione particolare. **Avvertenza:** non è un anticoncezionale, chiudere accuratamente dopo l'uso.

**ES** M EROS ANAL es un lubricante de uso médico con base de silicon para su utilización con condones de látex. Seguro para condones de látex, mejora el deslizamiento durante las relaciones íntimas, gran rendimiento, deja la piel suave y sedosa, dermatológicamente probado en cuanto a tolerabilidad de la piel y las mucosas, aceite y grasa libremente, incoloro e inodoro, insípido, está diseñado para contribuir a la lubricación y mejorar los juegos de sexo anales. **Utilización:** aplique EROS ANAL con la frecuencia y en la cantidad deseadas sobre los puntos del cuerpo en los que se desee humedad adicional. **Nota:** no es un anticonceptivo, cerrar cuidadosamente el envase después del uso.

Ingredients (INCI): Dimethicone and Dimethiconol, Cyclomethicone

Made in Germany

Art.-Nr. E 11410  
100 ml / 3,4 fl.oz  
LOT B/F 27

**EROS®**



**ANAL  
SILICONE**

for use with latex condoms

**DE** EROS ANAL ist ein medizinisches Gleitmittel auf Silikonbasis. Latexkondomsicher, verbessert die Gleitfähigkeit beim Analverkehr, sehr ergiebig, hinterlässt ein seidiges Hautgefühl, dermatologisch auf Haut- und Schleimhautverträglichkeit getestet, öl- und fettfrei, farb- und geruchlos, geschmacksneutral, keine Konservierungsstoffe. **Anwendung:** Geben Sie so häufig und so viel EROS ANAL wie gewünscht auf die Körperstellen, an denen Sie extra Feuchtigkeit wünschen. **Hinweis:** kein Verhütungsmittel, nach Gebrauch wieder sorgfältig verschließen.

**EN** EROS ANAL is a silicone-based medical lubricant for use with latex condoms, especially designed to help lubricate and enhance anal play. It improves lubrication for sexual intercourse, high yield, leaves a silky skin, dermatologically tested for skin and mucous membrane tolerance, oil and fat free, colourless and odourless, neutral tasting, no preservatives. **Application:** Place as much EROS ANAL as you want on the body parts where you require additional moisture as often as you need. **Note:** Not a contraceptive, reseal carefully after use.

**FR** EROS ANAL est un lubrifiant médical à base de silicon qui s'utilise avec des préservatifs en latex. Compatible avec les préservatifs en latex, améliore le pouvoir glissant du préservatif lors des rapports intimes, très abondant, laisse la peau satinée, tolérance testée dermatologiquement sur la peau et les muqueuses, sans huile et graisse, incolore et inodore, goût neutre, sans produits conservateurs, il est conçu pour lubrifier et augmenter les sensations produites par les jeux sexuels de la zone anale. **Utilisation :** Appliquez EROS ANAL aussi souvent et autant que vous le voulez sur les parties du corps où vous souhaitez une humidification supplémentaire. **Information :** Ce produit n'est pas un contraceptif, refermer soigneusement après usage.

## EROS ANAL SILICONE

dimethicone gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53389-410
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: 0THT5PCJ0R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53389-410-13	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(53389-410)

Revised: 12/2012

MEGASOL COSMETIC GMBH