M 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.

USES:

- HELPS LUBRICATING IN BODY MASSAGE
- 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

USES

• HELPS LUBRICATING IN BODY MASSAGE

KEEP OUT OF REACH OF CHILDREN DIMETHICONE 30%

DIMETHICONOL, CYCLOMETHICONE

- FOR EXTERNAL USE ONLY
- STOP USE AND ASK DOCTOR IF RASH OR IRRITATION DEVELOPES AND LASTS

Drug Facts		
Active Ingredients	Purpose	
Dimethicone 30%	Skin Protectant	

Uses:

Helps lubricating in body massage

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.



II M EROS Bodyglide è un lubrificante medicinale su base di Silicone. Sicurezza del preservativo in lattice, migliora la lubrificazione durante il rapporto, ad alto rendimento, rilascia su la pele 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, sensa Konservazinati. Utilizzo: applicate tutte le volte che lo desiderate quanto. EROS Bodyglide volete su quelle parti del corpo su cui desiderate un'idratazione particolare. Avvertenza: non è un anticoncezionale, custodire a temperatura ambiente, chiudere accuratamente dopo l'uso, non esporre all'irradiazione solare dretta.

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M EROS Bodyglide es un lubricante de uso médico con base de silicón. Seguro para condones de látex, mejora el deslizamiento durante las relaciones intimas, 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, insipido. Utilización: aplique EROS Bodyglide 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, almacenar a temperatura ambiente, cerrar cuidadosamente el envase después del uso, no dejar expuesto a la acción solar directa.

ingredients (INCI): Dimethicone and Dimethiconol, Cyclomethicone

Made in Germany

Art.-Nr. E 11041 100 ml / 3,4 fl.oz LOT I/C 09

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BODYGLIDE®

LUBRICANT

for use with latex condoms

TEROS Bodyglide ist ein medizinisches Gleitmittel auf Silikonbasis. Latexkondomsicher, verbessert die Gleitfähigkeit beim Intimverkehr, 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 Bodyglide wie gewünscht auf die Körperstellen, an denen Sie extra Feuchtigkeit wünschen. Hinweis: kein Verhütungsmittel, bei Raumtemperschließen, keiner direkten Sonneneinstrahlung aussetzen.

ED M EROS Bodyglide is a silicone-based medical lubricant. Suitable for use with latex condoms, 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 Bodyglide as you want on the body parts where you require additional moisture as often as you need. Note: Not a contraceptive, store at room temperature, reseal carefully after use, do not expose to direct sunlight.

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M EROS BODYGLIDE .SUPER CONCENTRATED

dimethicone gel

Product Information Product Type HUMAN OTC DRUG LABEL Item Code (Source) NDC:53389-110 Route of Administration TOPICAL DEA Schedule

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

Inactive Ingredients	
Ingredient Name	Strength
DIMETHICONOL (100000 CST)	
CYCLOMETHICONE	

# Item Code Package Description Marketing Start Date	Marketing End Date
1 NDC:53389-110-14 100 mL in 1 TUBE	

Marketing Info	rmation		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	12/0 1/20 12	

Labeler - MEGASOL COSMETIC GMBH (344152855)

Registrant - MEGASOL COSMETIC GMBH (344152855)

Establishment				
Name	Address	ID/FEI	Business Operations	
MEGASOL COSMETIC GMBH		344152855	manufacture(53389-110)	

Revised: 12/2012 MEGASOL COSMETIC GMBH