

EROS AQUA BASED- glycerin 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

GLYCERIN 5%

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: WATER (AQUA), ETHOXYDIGLYCOL, GUAR
HYDROXYPROPYLTRIMONIUM CHLORIDE, HYDROXYETHYLCELLULOSE, CITRIC ACID,
BENZYL ALCOHOL/METHYLISOTHIAZOLINONE/METHYLCHLOROISOTHIAZOLINONE

Drug Facts	
Active Ingredients	Purpose
Glycerin 5%	Skin Protectant
Uses:	
<ul style="list-style-type: none"> • Helps lubricating in body massage 	
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: Water, ethoxydiglycol, guar hydroxypropyltrimonium chloride, hydroxyethylcellulose, citric acid, benzyl alcohol, methylisothiazolinone, methylchloroisothiazolinone.	



M EROS GEL Aqua Based è un lubrificante medicinale su base d'acqua da applicare in combinazione con preservativi in lattice. Sicurezza del preservativo in lattice, migliora la lubrificazione durante il rapporto, ad alto rendimento, idratante, testato da un punto di vista dermatologico in merito a tolleranza su pelle e mucosa, solubile in acqua e privo di grassi, incolore e inodore, sapore neutro.
Utilizzo: applicate tutte le volte che lo desiderate quanto **M** EROS GEL Aqua Based 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 diretta.

M EROS GEL Aqua Based es un lubrificante de uso médico con base de agua para su utilización con condones de látex. Seguro para condones de látex, mejora el deslizamiento durante las relaciones íntimas, gran rendimiento, humectante, dermatológicamente probado en cuanto a tolerabilidad de la piel y las mucosas, hidrosoluble y exento de grasa, incoloro e inodoro, insípido.

Utilización: aplique **M** EROS GEL Aqua Based con la frecuencia y en la cantidad deseadas sobre los puntos del cuerpo en los que se desea 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):
 Aqua, Glycerin, Ethoxydiglycol, Guar Hydroxypropyltrimonium Chloride, Hydroxyethylcellulose, Citric Acid, Benzyl Alcohol/Methylisothiazolinone/Methylchlorisothiazolinone

Art.-Nr. E 60241
 100 ml / 3,4 fl.oz

LOT F/E 30

M
EROS[®]



GEL
AQUA BASED

lubricant for use with latex condoms
 Made in Germany

M EROS GEL Aqua Based ist ein medizinisches Gleitmittel auf Wasserbasis zur Anwendung mit Latexkondomen. Latexkondomsicher, verbessert die Gleitfähigkeit beim Intimverkehr, sehr ergiebig, feuchtigkeitsspendend, dermatologisch auf Haut- und Schleimhautverträglichkeit getestet, wasserlöslich und fettfrei, farb- und geruchlos, geschmacksneutral.

Anwendung: Geben Sie so häufig und so viel **M** EROS GEL Aqua Based wie gewünscht auf die Körperstellen, an denen Sie extra Feuchtigkeit wünschen.

Hinweis: kein Verhütungsmittel, bei Raumtemperatur lagern, nach Gebrauch wieder sorgfältig verschließen, keiner direkten Sonneneinstrahlung aussetzen.

M EROS GEL Aqua Based is a water-based medical lubricant for use with latex condoms. Suitable for use with latex condoms, improves lubrication for sexual intercourse, high yield, moisturising, dermatologically tested for skin and mucous membrane tolerance, water-soluble and grease-free, colourless and odourless, neutral tasting.

Application: Place as much **M** EROS GEL Aqua Based 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.

M EROS GEL Aqua Based est un lubrifiant médical à base d'eau 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, humidifiant, tolérance testée dermatologiquement sur la peau et les muqueuses, soluble dans l'eau et non gras, incolore et inodore, goût neutre.

Utilisation : Appliquez **M** EROS GEL Aqua Based 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, entreposer à température ambiante, refermer soigneusement après usage, ne pas exposer au rayonnement solaire direct.

MEGASOL
 COSMETIC GMBH

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EROS AQUA BASED

glycerin gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53389-241
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	30 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A118X02B)	

GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)	
HYDROXYETHYL CELLULOSE (100 MPAS AT 2%) (UNII: R33S7TK2EP)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53389-241-13	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(53389-241)

Revised: 12/2012

MEGASOL COSMETIC GMBH