#### M EROS LIQUID 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.

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ACTIVE INGREDIENT

**GLYCERIN 5%** 

**PURPOSE** 

SKIN PROTECTANT

**USES** 

HELPS LUBRICATING IN BODY MASSAGE

#### **WARNINGS**

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

#### **DIRECTIONS FOR USE**

- APPLY AS NEEDED
- OPEN 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
- HYDROXYPROPYL GUAR
- HYDROXYPROPYLTRIMONIUM CLORIDE
- HYDROXYETHYLCELLULOSE
- CITRIC ACIS
- PHENOXYETHANOL
- ETHYLHEXLGLYCERIN

KEEP OUT OF REACH OF CHILDREN

| Drug Facts         |                 |
|--------------------|-----------------|
| Active Ingredients | Purpose         |
| Glycerin 5%        | Skin Protectant |

### Uses:

Helps lubricating in body massage

## Warnings:

- 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: Water, hydroxypropyl guar, hydroxypropyltrimonium chloride, hydroxyethylcellulose, citric acid, phenoxyethanol, ethylhexylglycerin.



lubrificante medicinale su base d'acqua. 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 pele
mucose, solubile in acqua e privo di grassi,
incolore e inodore, sapore neutro. Utilizzo:
applicate tutte le volte che lo desiderate
quanto EROS LIQUID 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.

COSMETIC GMIBH
Sinren b Trier, GERMANY, Jean-Monne
49 (b) 6502 / 2001; Fax 49 (b) 6502 / 2001; Fax 49 megasol, de - www.eros-bodyglis

M EROS LIQUID Aqua Based es un inbricante de uso médico con base de agua. Seguro para condones de látex, mejora desilizamiento durante las relaciones intimas, gran rendimiento, humectante, dermatológicamente probado en cuanto a tolerabilidad de la piel y las mucosas, hidrosoluble exento de grasa, incoloro e inodoro, insípido. Utilización: aplique EROS LIQUID Aqua Based con la frecuencia y en la cantidad deseadas sobre los puntos del cuerpo en los que se desse 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, Hydroxypropyl Guar Hydroxypropyltrimonium Chloride, Hydroxyethylcellulose, Citric Acid, Phenoxyethanol, Ethylhexylglycerin

Made in Germany

TOPICAL

Art.-Nr. E 60061 250 ml / 8,5 fl.oz LOT I/G 29



for use with latex condoms

**DEA** Schedule

■ M EROS LIQUID Aqua Based ist ein medizinisches Gleitmittel auf Wasserbasis. Latexkondomsicher, verbessert die Gleitfähigkeit beim Intimverkehr, sehr ergiebig, feuchtigkeitspendend, dermatologisch auf Haut- und Schleimhautverträglichkeit getestet, wasserlöslich und fettfrei, farb- und geruchlos, geschmacksneutral. Anwendung: Geben Sie so häufig und so viel EROS LIQUID 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 LIQUID Aqua Based is a water-based medical lubricant. 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, colouriess and odouriess, neutral tasting. Application: Place as much EROS LIQUID Aqua Based as you want on the BOS 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 sunliont.

M EROS LIQUID Aqua Based est u lubrifiant médical à base d'eau. Compatible avec les préservatifs en latex, améliore i pouvoir glissant du préservatif lors de rapports intimes, très abondant, humidifiant tolérance testée dermatologiquement sur le peau et les muqueuses, soluble dans l'eau e non gras, incolore et inodore, goût neutre Utilisation: Appliquez EROS LIQUID Aque Based aussi souvent et autant que vous ouvelz sur les parties du corps où vous sou haitez une humidification supplémentaire information: Ce produit n'est pas un contra ceptif, entreposer à température ambiante refermer solgneusement après usage, ne pa exposer au ravonnement solare direct.





**Route of Administration** 

## M EROS LIQUID AQUA BASED

glycerin gel

# Product Information Product Type HUMAN OTC DRUG LABEL Item Code (Source) NDC:53389-600

Active Ingredient/Active Moiety

Ingredient Name
Basis of Strength

GLYCERIN (GLYCERIN)

GLYCERIN

5 g in 100 mL

| Inactive Ingredients                       |          |  |
|--|----------|--|
| Ingredient Name                            | Strength |  |
| WATER                                      |          |  |
| HYDROXYPROPYL GUAR (2500-4500 MPA.S AT 1%) |          |  |
| DIHYDRO XYPRO PYLTRIMO NIUM CHLO RIDE      |          |  |
| HYDROXYETHYL CELLULOSE (100 MPA.S AT 2%)   |          |  |

| ANHYDRO US CITRIC ACID |  |
|------------------------|--|
| PHENO XYETHANO L       |  |
| ETHYLHEXYLGLYCERIN     |  |
|                        |  |

| Packaging |                  |                     |                      |                    |
|-----------|------------------|---------------------|----------------------|--------------------|
| #         | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
| 1         | NDC:53389-600-14 | 250 mL in 1 TUBE    |                      |                    |

| Marketing Information |  |                      |                    |
|-----------------------|--|----------------------|--------------------|
| 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)

| Establishment         |         |           |                        |  |
|-----------------------|---------|-----------|------------------------|--|
| Name                  | Address | ID/FEI    | Business Operations    |  |
| MEGASOL COSMETIC GMBH |         | 344152855 | manufacture(53389-600) |  |

Revised: 12/2012 MEGASOL COSMETIC GMBH