

MANUGEL 85- ethanol gel
Laboratoires Anios

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.

Thixotropic hydroalcoholic gel for hygienic treatment and surgical disinfection by hand-rubbing.

Ethanol (700 mg/g ie 755 ml/l - N° CAS 64-17-5) in the presence of thickening, moisturizing and emollient agents, and water. Without perfume nor coloring.

Bactericidal: EN 1040, pr EN 12054, EN 1500, EN 12791. Tuberculocidal: EN 14348. Yeasticidal EN 1275, EN 1650. Virucidal: EN 14476+A1 (30 sec.). Active against HIV-1, PRV (surrogate of HBV), BVDV (surrogate of HCV), Rotavirus, Herpes virus, Coronavirus, Norovirus, Influenza virus A [H1N1] and Influenza virus A NIBRG14 [H5N1].

A ready-to-use gel. **Hygienic treatment:** 3 ml* for a hand-rubbing time of 30 seconds. **Surgical disinfection:** 2 x 3 ml* for a hand-rubbing time of two times 45 seconds. Well-apply and rub until complete dry. Do not rinse. (*3 ml = 2 pump squirts). For application in operating theater and frequency of use, refer to the protocol of the establishment.

Hygienic treatment: 3 ml* for a hand-rubbing time of 30 seconds. Surgical disinfection: 2 x 3 ml* for a hand-rubbing time of two times 45 seconds. Well-apply and rub until complete dry. Do not rinse. (*3 ml = 2 pump squirts).

Topical route exclusively. Flammable. Keep away from sources of ignition - no smoking. Avoid contact with eyes. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. If swallowed, seek medical advice immediately and show this container or label. If necessary, contact the poison control center. Keep out of reach of children. Do not dispose of product directly into the environment. Do not reuse the packaging. This material and the container must be disposed of in a safe way. Use of the product in accordance with the use instructions does not alter the requirements in terms of air extraction volume. Storage: from +5°C to +25°C. Human hygiene biocidal product (Main Group 1 - PT1 - directive 98/8/EC). Professional use. Made in France.

Keep out of reach of children.

Thixotropic hydroalcoholic gel for hygienic treatment and surgical disinfection by hand-rubbing

Active ingredient in the presence of thickening, moisturizing and emollient agents, and water. Without perfume nor coloring.

Topical route exclusively. Flammable. Keep away from sources of ignition - no smoking. Avoid contact with eyes. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. If swallowed, seek medical advice immediately and show this container or label. If necessary, contact the poison control center. Keep out of reach of children. Do not dispose of product directly into the environment. Do not reuse the packaging. This material and the container must be disposed of in a safe way. Use of the product in accordance with the use instructions does not alter the requirements in terms of air extraction volume. Storage: from +5°C to +25°C. Human hygiene biocidal product (Main Group 1 - PT1 - directive 98/8/EC). Professional use. Made in France.



MANUGEL 85

Disinfectant gel for hydroalcoholic handrubbing

INDICATIONS : Thixotropic hydroalcoholic gel for hygienic treatment and surgical disinfection by handrubbing.

COMPOSITION : Ethanol (750.7 mg/g ie +/- 800ml/l - N° CAS 64-17-5), 2-phenoxyethanol (0.6 mg/g ie +/- 0.5ml/l - N° CAS 122-99-6), excipients.

MICROBIOLOGICAL PROPERTIES : Bactericidal: EN 1040, pr EN 12054, EN 1500, EN 12791. Active against *M. terrae*. Active against HIV-1, PRV (surrogate of HBV), BVDV (surrogate of HCV), Herpes virus, Rotavirus, Coronavirus, Adenovirus, Influenza virus A NIBRG14 [H₅N₁], Influenza virus A [Swine H₁N₁], Poliovirus (NF T 72-180/30 sec).

INSTRUCTIONS FOR USE : Ready-to-use gel. **Hygienic treatment**: 3 ml* - 30 seconds. **Surgical disinfection**: 2 x 4.5 ml* - 3 minutes. Distribute the product well until completely dry. Do not rinse. For application in the operating theatre and frequencies of use, please refer to the hygiene plan in place. (*1 pump squirt = 1.5 ml).

PRECAUTIONS FOR USE : Keep away from sources of ignition - no smoking. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. If swallowed, seek medical advice immediately and show this container or label. If necessary, contact the poison

control centre. Keep out of reach of children. Do not re-use packaging. Do not dispose of product directly into the environment. This material and its container must be



**HIGHLY
FLAMMABLE**

disposed of as hazardous waste. Use of the product in accordance with the user instructions does not alter the requirements in terms of air extraction volume. Store between +5°C and +25°C. Human hygiene biocidal product (Main group - PT 1 – Directive 98/8/EC) - professional use.



Laboratoires

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LOT: N08016S

FAB: 03/2011

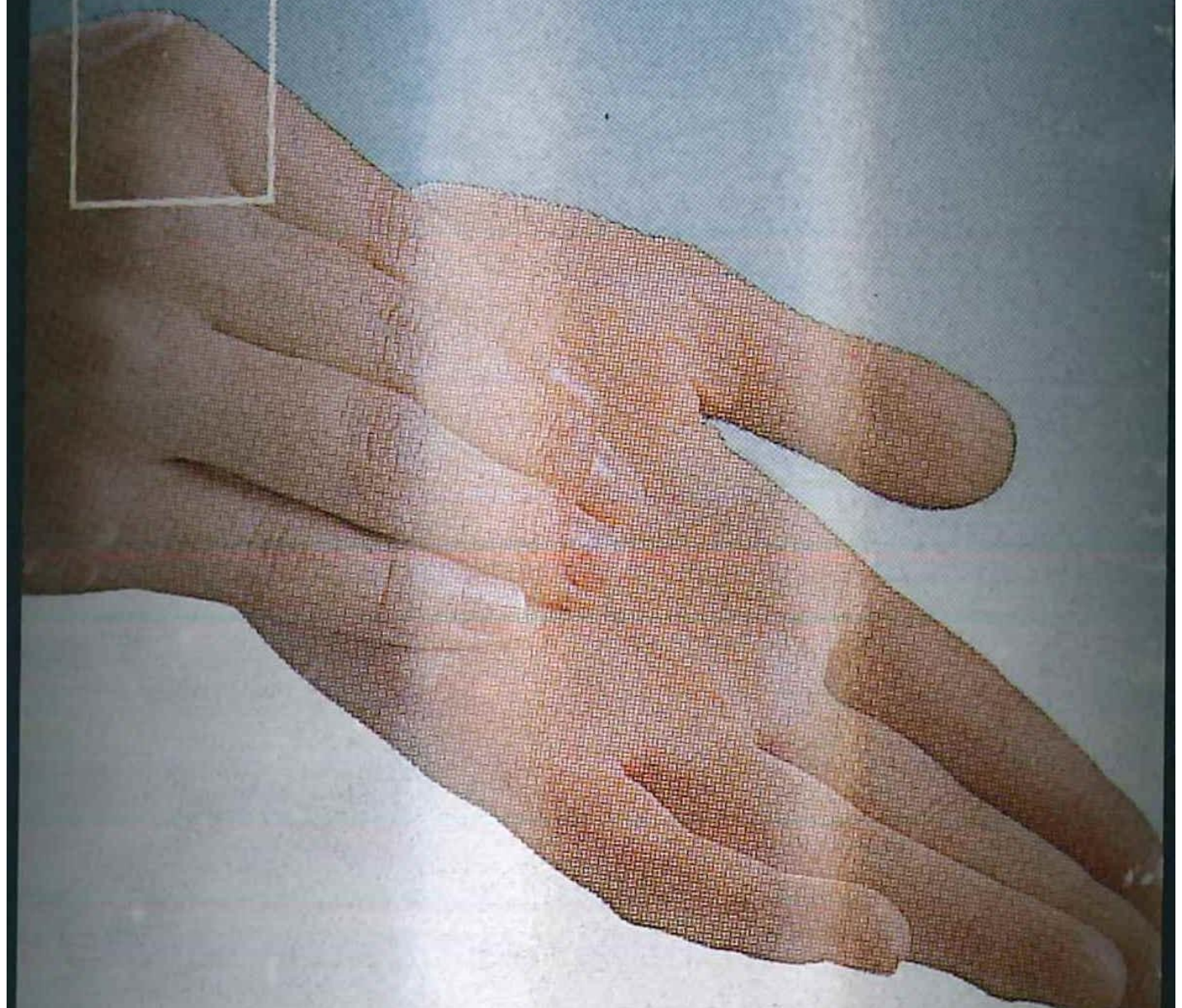
EXP: 03/2014

This product has been conceived according to a Quality organization complying with the ISO 9001 standard which is certified by AFAQ under the number 1995/3723.

GB15150500MADV-091204

MANUGEL 85

**Gel désinfectant
pour friction
hydroalcoolique**





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Le professionnel de la désinfection

500 ml

1515RU-2007.07A

MANUGEL 85

ethanol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62169-202
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	400 mL in 500 mL
PHENOXYETHANOL (UNII: HIE492ZZ3T) (PHENOXYETHANOL - UNII:HIE492ZZ3T)	PHENOXYETHANOL	0.3 g in 500 mL

Inactive Ingredients

Ingredient Name	Strength
Glycerin (UNII: PDC6A3C0OX)	99.7 mL in 500 mL

Product Characteristics

Color		Score	
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Shape	FREEFORM	Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62169-202-12	12 in 1 PACKAGE		
1	NDC:62169-202-17	500 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/01/2014	

Labeler - Laboratoires Anios (274758465)

Establishment

Name	Address	ID/FEI	Business Operations
Laboratoires Anios		274758465	manufacture(62169-202)

Revised: 3/2014

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