

ANIOSGEL 85 NPC- 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.

☐Indications & Usage:

HYDROALCOHOLIC ANTISEPTIC GEL FOR SKIN AND HANDS

Active Ingredients Purpose

Ethanol 70.0% (w/w)Antisepsis

Instructions for Use/Directions

Hygienic Treatment: Apply 3 ml of gel to cupped palm of hands. Rub fingertips and hands thoroughly until completely dry, for at least 30 seconds.

Surgical disinfection: 2 x 3 ml for a hand rubbing time of 2 x 45 seconds.

- Do not rinse

For Dosage and Administration, please refer to "INSTRUCTIONS FOR USE SECTION"

Warnings and Precautions

For external use only

- Do not swallow
- Keep away from heat source
- If accidental eye contact occurs, rinse thoroughly with water
- If irritation persists, consult a physician

In case of ingestion, get medical help or contact a Poison Control Center right away.

Keep out of reach of children.

OTC Purpose/Use

- Hygienic treatment
- Surgical disinfection

☐Inactive Ingredients:

Inert ingredients 30.0% (w/w)

For Warnings, please refer to "WARNINGS AND PRECAUTIONS SECTION"

☐FRONT LABEL

ANIOSGEL 85 *NPC*

Hydroalcoholic
antiseptic gel for
hand rubbing





17 fl. oz (500 ml)




Laboratoires

ANIOS

Le professionnel de la désinfection

CF16440500MADR-140403

BACK LABEL



ANIOSGEL 85 NPC

Drug Facts

HYDROALCOHOLIC ANTISEPTIC GEL FOR SKIN AND HANDS

Active Ingredients	Purpose
Ethanol 70.0% (w/w)	Antisepsis

Uses

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- Surgical disinfection

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• KEEP AWAY FROM HEAT SOURCE

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Directions

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• Do not rinse

Other information

• Does not require water

• Store at 5 - 25 °C (41 - 77 °F)

• Highly flammable

Inactive Ingredients

Inert ingredients 30.0% (w/w)

17 fl. oz (500 ml)



ANGELINI

Distributor/Importer:
Angelini Pharma Inc.
Gaithersburg, MD 20877
(800)726-2308
www.angelini-us.com



Manufactured by:
Laboratoires ANIOS
Lille, Hellemmes, France



CF1644855500MADV-140403

ethanol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62169-203
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	377.5 mL in 500 mL

Inactive Ingredients

Ingredient Name	Strength
Glycerin (UNII: PDC6A3C0OX)	122.5 mL in 500 mL

Product Characteristics

Color		Score	
Shape	FREEFORM	Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62169-203-12	12 in 1 PACKAGE		
1	NDC:62169-203-17	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(62169-203)