

ISAGEL- alcohol gel
Coloplast Manufacturing US, LLC

ISAGEL®

Drug Facts

Active ingredient

60% v/v Alcohol Denat

Purpose

Antiseptic Healthcare Personnel Hand Wash

Uses

For handwashing to decrease bacteria on the skin.

Warnings

Flammable, keep away from fire or flame.

When using this product

- avoid contact with eyes. If eye contact occurs, flush with water.

Stop using this product

- if skin irritation and redness develop
- if condition persists for more than 72 hours, consult a physician.

For external use only.

Keep this and all drugs out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Wet hands thoroughly. Rub product into hands and allow to dry. Do not rinse. Wash hands with water and hand cleanser after every 7-9 applications. For use when hands are not visibly soiled.

Inactive ingredients

carbomer, fragrance, glycereth-26, PEG-12, triethanolamine, water

Questions or comments

Call toll free 1-800-533-0464

Manufactured by: Coloplast A/S
Holtedam 1
DK-3050 Humlebaek, Denmark
Distributed by: Coloplast Corp.
1601 W River Rd N
Minneapolis, MN 55411 U.S.A.

PRINCIPAL DISPLAY PANEL - 118 mL Bottle Label

NDC 11701-025-04

Latex
Glove and CHG
Compatible

Isagel[®]

Handwashing

No-Rinse,
Antiseptic Hand
Cleansing Gel
with Added
Moisturizers

For Healthcare
Personnel
Handwashing

Product #1644

Coloplast

4 fl. oz. (118 mL)

F15-1111

NDC 11701-025-04

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Glove and CHG
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Meets the CDC Hand Hygiene Guideline
in Health-Care settings.

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F15-1112

Drug Facts (continued)

Warnings

Flammable, keep away from fire
or flame. When using this product
■ avoid contact with eyes. If eye
contact occurs, flush with water.
Stop using this product ■ if skin

Stop using this product ■ if skin irritation and redness develop ■ if condition persists for more than 72 hours, consult a physician.
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F15-1112

ISAGEL

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11701-025
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Alcohol (UNII: 3K9958V90M) (Alcohol - UNII:3K9958V90M)	Alcohol	600 mL in 1000 mL

Inactive Ingredients

Ingredient Name	Strength
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
GLYCERETH-26 (UNII: NNE56F2N14)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	

WATER (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11701-025-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/15/2009	
2	NDC:11701-025-26	621 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/15/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph drug	M003	06/15/2009	

Labeler - Coloplast Manufacturing US, LLC (110326675)

Registrant - Coloplast Corp (847436391)

Establishment

Name	Address	ID/FEI	Business Operations
Coloplast Manufacturing US, LLC		110326675	MANUFACTURE(11701-025)

Revised: 12/2023

Coloplast Manufacturing US, LLC