ISOPROPYL ALCOHOL WITH WINTERGREEN 50% - is opropyl alcohol with wintergreen 50% solution

Hydrox Laboratories

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.

Isopropyl Alcohol

Drug Facts

Active Ingredient

Isopropyl Alcohol 50%

Purpose:

First Aid Antiseptic

Uses first aid to help prevent the risk of infection in: minor cuts, scrapes, burns.

Warnings For external use only

Flammable

- Keep away from fire or flame, heat, spark, electrical. Flash point 72°F.
- do not use with eletocautery procedures.

Ask a doctor before use if you have Ideep or puncture wounds, animal bites or serious burns.

When using this product

- do not get into eyes
- do not apply over large areas of the body
- do not use longer than 1 week unless directed by a doctor

Stop use and ask a doctor lif condition persists or gets worse

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

Directions □•clean the affected area • apply 1 to 3 times daily • may be covered with a sterile bandage • if bandaged, let dry first

Other information Idoes not contain, nor is intended as a substitue for grain or ethyl alcohol. will produce serious gastric disturbances if taken internally.

Inactive Ingredient

FD&C Blue No. 1, FD&C Yellow No. 5, Methyl Salicylate, PEG-75 Lanolin, Purified Water

Principal Display Panel



NDC 10565-007-99

ISOPROPYL ALCOHOL with WINTERGREEN FIRST AID ANTISEPTIC



Net Content: ONE GALLON (3.8 L)



Mfg. by Hydrox LABORATORIES Elgin, IL 60123 • www.hydroxlabs.com

Drug Facts

Active ingredient Isopropyl alcohol 50%...

Purpose First Aid Antiseptic

Uses helps prevent the risk of infection in • minor cuts • scrapes

Warnings For external use only

Flammable • keep away from fire or flame, heat, spark, electrical

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1-07-A0073

Reorder A0073

Hydrox

Isopropyl Alcohol 50% with Wintergreen

A cooling and refreshing and massaging compound

First Aid Antiseptic

TAMPER EVIDENT CAP FOR YOUR PROTECTION. IF RING-BAND IS DETACHED FROM CAP OR MISSING, DO NOT USE.

WARNING: FLAMMABLE!

Hydrox Laboratories

Elgin, IL 60123



NDC 10565-007-99

ISOPROPYL ALCOHOL with WINTERGREEN FIRST AID ANTISEPTIC



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Drug Facts

Active ingredient Purpose Isopropyl alcohol 50%..... First Aid Antiseptic

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1-07-A0073

Reorder A0073

ISOPROPYL ALCOHOL WITH WINTERGREEN 50%

isopropyl alcohol with wintergreen 50% solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10565-007
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Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	50 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)			
METHYL SALICYLATE (UNII: LAV5U5022Y)			
PEG-75 LANOLIN (UNII: 09179 OX7TB)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10565-007- 04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/19/2019	
2	NDC:10565-007- 08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/19/2019	
3	NDC:10565-007- 16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/19/2019	
4	NDC:10565-007- 32	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/19/2019	
5	NDC:10565-007- 99	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/19/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/19/2019	

Labeler - Hydrox Laboratories (025164302)

Registrant - Hydrox Laboratories (025164302)

Establishment				
Name	Address	ID/FEI	Business Operations	
Hydrox Laboratories		025164302	manufacture(10565-007), label(10565-007), pack(10565-007)	

Revised: 11/2019 Hydrox Laboratories