ONKO HEALTH ALCOHOL ANTISEPTIC WIPE- alcohol, isopropyl alcohol cloth
ONKO PHARMACEUTICALS USA INC.

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.

Active Ingredients

Alcohol 60% v/v.

Isopropyl alcohol 10 % v/v.

Purpose

Antiseptic

Use

- For sanitizing skin.
- Suitable for hygienic personal care and disinfectant cleansing within private spaces.
- For preparation of the skin prior to injection or venipuncture.

Warnings

For external use only.

Flammable. Keep away from heat or flame.

Do not use

- with electrocautery procedures
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs.

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

Directions

For single pack;

• Tear open pouch, remove towel.

• Wipe injection site vigorously and discard. / Wet hands and wrists thoroughly for 15 seconds and discard.

• Supervise children under 6 years of age.

For multi pack;

• Open clip-lid.

• Remove moist towels to clean skin as required.

• Wipe injection site vigorously and discard. / Wet hands and wrists thoroughly for 15 seconds and

discard.

• Close lid when not in use to keep remaining towels moist.

• Supervise children under 6 years of age.

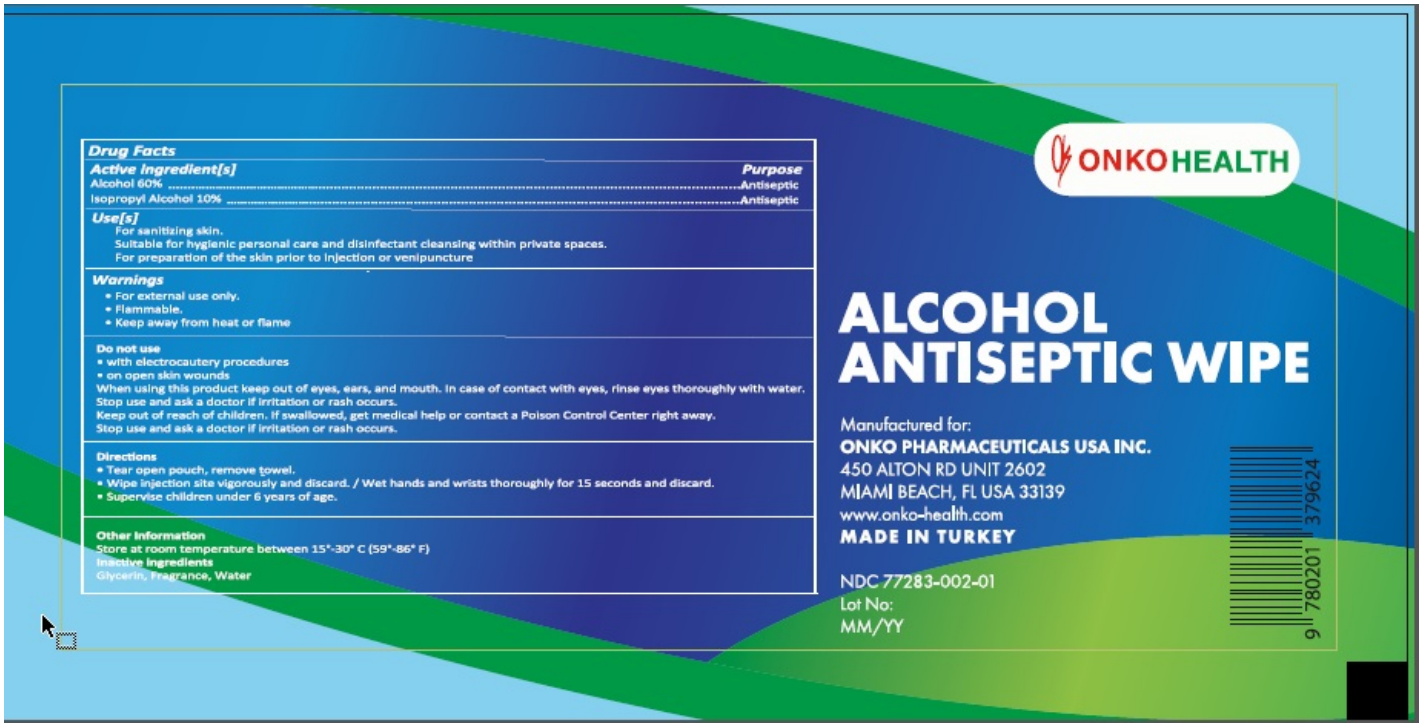
Other information

- Store between 15-30°C (59-86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients

Glycerin, Fragrance, Water.

Package Label - Principal Display Panel



ONKO HEALTH ALCOHOL ANTISEPTIC WIPE

alcohol, isopropyl alcohol cloth

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:77283-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	60 mL in 100 mL
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	10 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77283-002-01	1 in 1 POUCH	07/13/2020	
1		5 mL in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
	NDC:77283-002			

2	NDC:77283-002-02	100 in 1 BOTTLE, PLASTIC	07/13/2020	
2		3.12 mL in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
3	NDC:77283-002-03	120 in 1 BOTTLE, PLASTIC	07/13/2020	
3		3.12 mL in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
4	NDC:77283-002-04	150 in 1 BOTTLE, PLASTIC	07/13/2020	
4		3.12 mL in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
5	NDC:77283-002-05	350 in 1 BOTTLE, PLASTIC	07/13/2020	
5		3.12 mL in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
6	NDC:77283-002-06	400 in 1 BOTTLE, PLASTIC	07/13/2020	
6		3.12 mL in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
7	NDC:77283-002-07	450 in 1 BOTTLE, PLASTIC	07/13/2020	
7		3.12 mL in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
8	NDC:77283-002-08	500 in 1 BOTTLE, PLASTIC	07/13/2020	
8		3.12 mL in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
9	NDC:77283-002-09	550 in 1 BOTTLE, PLASTIC	07/13/2020	
9		3.12 mL in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
10	NDC:77283-002-10	600 in 1 BOTTLE, PLASTIC	07/13/2020	
10		3.12 mL in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
11	NDC:77283-002-11	700 in 1 BOTTLE, PLASTIC	07/13/2020	
11		3.12 mL in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
12	NDC:77283-002-12	800 in 1 BOTTLE, PLASTIC	07/13/2020	
12		3.12 mL in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
13	NDC:77283-002-13	900 in 1 BOTTLE, PLASTIC	07/13/2020	
13		3.12 mL in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
14	NDC:77283-002-14	1000 in 1 BOTTLE, PLASTIC	07/13/2020	
14		3.12 mL in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
15	NDC:77283-002-15	2000 in 1 BOTTLE, PLASTIC	07/13/2020	
15		3.12 mL in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
16	NDC:77283-002-16	5000 in 1 BOTTLE, PLASTIC	07/13/2020	
16		3.12 mL in 1 NOT APPLICABLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/13/2020	

Labeler - ONKO PHARMACEUTICALS USA INC. (114603246)

Establishment

Name	Address	ID/FEI	Business Operations
SEKTOR KIMYA DETERJAN SANAYI VE TICARET ANONIM SIRKETI		533132559	manufacture(77283-002)

Revised: 11/2020 ONKO PHARMACEUTICALS USA INC.