PROSERA SOOTHING HAND SANITIZING WIPES- alcohol cloth
D-Time Limited Liability Company

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 Ingredient

Alcohol 80% v/v.

Purpose

Antiseptic skin cleanser

Uses

For personal hand hygiene to help prevent the spread of bacteria.

Warnings

For external use only.
When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water.
Stop use and consult a healthcare professional if irritation develops.

Flammability warning: Flammable. Keep away from open flame and sources of heat.

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

Directions

Adults and children over 2 years. For occasional and personal domestic use. Supervise children when they use this product. Rub thoroughly into hands for at least 30 seconds. Allow to dry.

Other information

- Store at 68-70 ^{0}F (20-25 ^{0}C)
- May discolor certain fabrics or surfaces.

Inactive ingredients

Water (Aqua), Isopropyl alcohol, Glycerin, Hyaluronic acid, Allantoin, Vitamin E, Vetiver Oil, Sage Oil, Hydrogen peroxide

Package Label - Principal Display Panel

PROSERA SOOTHING HAND SANITIZING WIPES

alcohol cloth

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:75306-011
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYALURONIC ACID (UNII: S270N0TRQY)	
ALLANTOIN (UNII: 344S277G0Z)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
VETIVER OIL (UNII: 9M9P32M01L)	
SAGE OIL (UNII: U27K0H1H2O)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75306-011-01	1 in 1 POUCH	06/01/2020	
1		2 mL in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
2	NDC:75306-011-02	10 in 1 POUCH	06/01/2020	
2		2 mL in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
3	NDC:75306-011-03	20 in 1 POUCH	06/01/2020	
3		2 mL in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
4	NDC:75306-011-04	50 in 1 POUCH	06/01/2020	
4		2 mL in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
5	NDC:75306-011-05	100 in 1 POUCH	06/01/2020	
5		2 mL in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
6	NDC:75306-011-06	250 in 1 POUCH	06/01/2020	
6		2 mL in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
7	NDC:75306-011-07	50 in 1 CONTAINER	06/01/2020	
7		2 mL in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
8	NDC:75306-011-08	100 in 1 CONTAINER	06/01/2020	
8		2 mL in 1 NOT APPLICABLE; Type 0: Not a Combination Product		
9	NDC:75306-011-09	250 in 1 CONTAINER	06/01/2020	
9		2 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	06/01/2020	

Labeler - D-Time Limited Liability Company (081728006)

Revised: 11/2021

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