X-PROUSA ANTISEPTIC HAND SANITIZER GEL, CLEAN AND FRESH SCENT- alcohol gel
X-PROUSA LLC

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.

X-PROUSA Antiseptic Hand Sanitizer Gel, Clean and Fresh Scent

Drug Facts

Active ingredient

Ethyl alcohol 72%

Purpose

Antiseptic

Use

- Hand sanitizer to help reduce bacteria on the skin that could cause disease.
- Recommended for repeated use

Warnings

- For external use only.
- Flammable. Keep away from heat or flame

Do not use

- Do not use on children less than 2 months of age.
- Do not use 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. These may be signs of a serious condition.

Keep out of reach of children.

- If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Place enough product on hands to cover all surfaces.
- Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

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

Inactive ingredients

Water (Aqua), Glycerin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aminomethyl Propanol, Tocopherol Acetate, Fragrance(s)

Package Labeling:30ml

Package Labeling:60ml

Package Labeling:118ml

Package Labeling:240ml

Package Labeling:470ml

Package Labeling:950ml

Package Labeling:3800ml

X-PROUSA ANTISEPTIC HAND SANITIZER GEL, CLEAN AND FRESH SCENT

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:79490-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.72 mL in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:79490-001-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/21/2020	
2	NDC:79490-001-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/21/2020	
3	NDC:79490-001-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/21/2020	
4	NDC:79490-001-08	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/21/2020	
5	NDC:79490-001-16	470 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/21/2020	
6	NDC:79490-001-32	950 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/21/2020	
7	NDC:79490-001-38	3800 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/21/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/21/2020	

Labeler - X-PROUSA LLC (117567866)

Revised: 8/2020 X-PROUSA LLC