XEPI RUB ET HAND SANITIZING HANDRUB- ethyl alcohol solution
Sanmed Healthcare Private Limited

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.

SANMED ACTIVE HYGIENE
XEPI™ Rub ET HAND SANITIZING HANDRUB

DRUG FACTS

Active ingredients

Ethyl Alcohol 80.0% v/v

Purpose

Antiseptic Handrub

Uses:

* A hand rub to decrease microbial load on the skin

Warnings:

* For external use only

* Flammable. Keep away from fire or flame, heat sparks and sources of static discharge.

When using this product:

* Keep out of Eyes, Ears and Mouth.

* In case of contact with eyes, rinse promptly & thoroughly with water.

* Discontinue use if irritation and redness develop.

Stop use and ask a doctor if skin irritation or redness occurs for more than 72 hours.

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

Directions:

* Apply product onto hands, spread thoroughly & rub until dry.

Other information:

* Store below 30°C

* See Safety Data Sheet (SDS)

* For emergency medical information in USA, call .....

Inactive ingredients:

Hydrogen Peroxide 0.125% v/v, Water (aqua), Glycerin, Carbomer 940, Aminomethyl Propanol, Dettol Frag.

Questions or comments?

* Call: +91 40 4221 2432 / 33

* Email: info@sanmed.in

World Health Organization Recommended Formulation

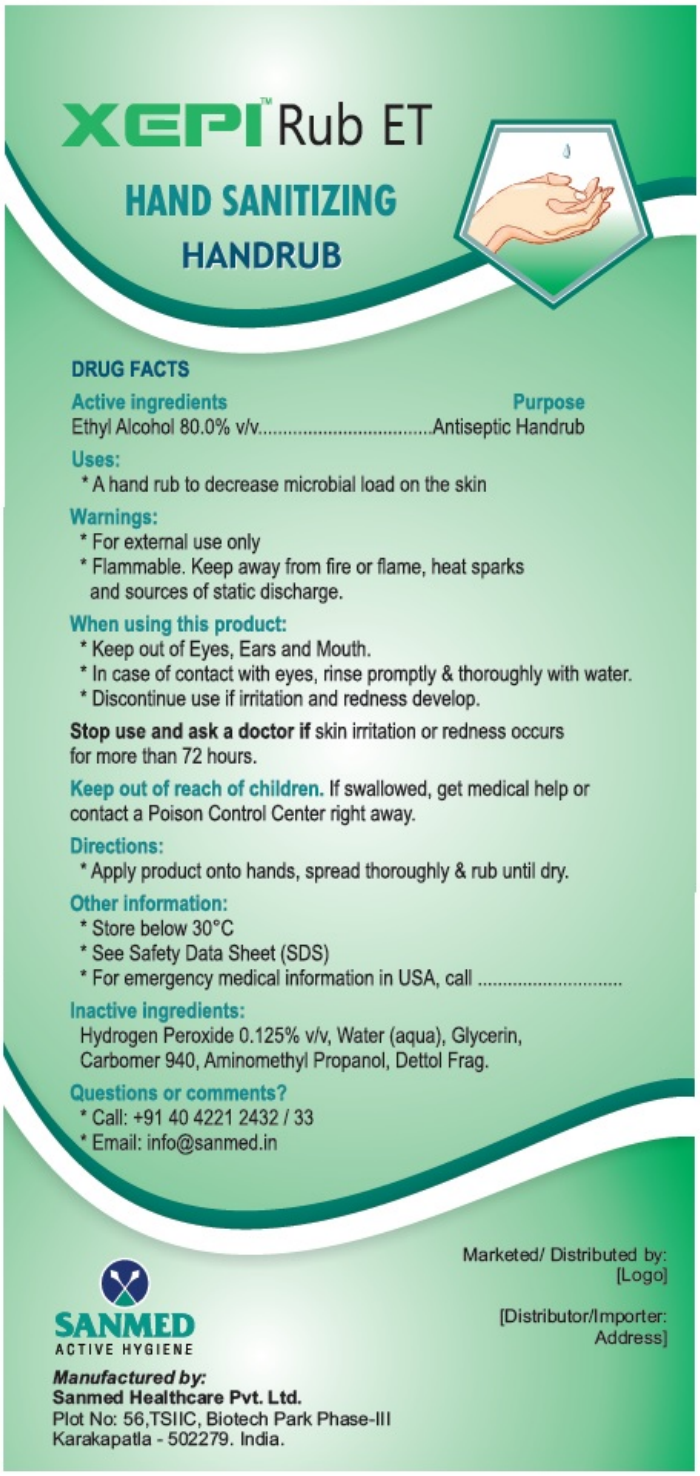
Manufactured by:

Sanmed Healthcare Pvt. Ltd.

Plot No: 56, TSIIC, Biotech Park Phase-III

Karakapatla - 502279. India.

Packaging



XEPI RUB ET HAND SANITIZING HANDRUB

ethyl alcohol solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:81357-101
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
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81357-101-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/28/2020	
2	NDC:81357-101-02	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/28/2020	
3	NDC:81357-101-03	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/28/2020	
4	NDC:81357-101-04	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/28/2020	
5	NDC:81357-101-05	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/28/2020	
6	NDC:81357-101-06	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/28/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	12/28/2020	

Labeler - Sanmed Healthcare Private Limited (854248431)

Establishment

Name	Address	ID/FEI	Business Operations
Sanmed Healthcare Private Limited		854248431	manufacture(81357-101)

Revised: 12/2020 Sanmed Healthcare Private Limited