

KTM POWER HAND- ethyl alcohol gel
Regenera y Transforma, S.A. de C.V.

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.

KTM POWER HAND HAND SANITIZER

Drug facts

Active ingredients

Ethyl alcohol 70% v/v

purpose

antiseptic

Use[s]

Hand sanitizer to help reduce bacteria that potentially can cause disease. for use when soap and water are not available.

Warnings

For external use only.

Flammable. Keep away from heat or flame.

When using this product

Do not use on open skin wounds.

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

Do not use in children less than 2 months of age.

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

Directions

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

Other information

Store between 15-30C (59-86F)

Avoid freezing and excessive heat above 40C (104F)

Inactive Ingredients

Water, Carbomer homopolymer Type C, Glycerin, Triethanolamine.

NO RINSING

70% ALCOHOL

"KILLS THE MOST GERMS"

Moisturizing

ANTISEPTIC

HAND RUB

ventas@kaizentm.com

Distributed by:

Kaizen Transfer of USA LLC.

611 Shiloh Dr, Ste. 5 Laredo, TX. 78045

Manufactured by:

Regenera y Transforma S.A.de C.V.

Made in México

Packaging

Drug facts NDC 78499-100-05

Active ingredients	purpose
Ethyl alcohol 70% v/v	antiseptic

Use(s)
Hand sanitizer to help reduce bacteria that potentially can cause disease, for use when soap and water are not available.

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

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KTM POWER HAND

HAND SANITIZER



70% ALCOHOL

NO RINSING

128 FL OZ (3.78 LITERS)

HAND SANITIZER

KTM POWER HAND

NO RINSING **70% ALCOHOL**

"KILLS MOST GERMS"



ANTISEPTIC HAND RUB

33.8 FL OZ (1,000 ML)

Drug facts NDC 78499-100-01

Active ingredients	purpose
Ethyl alcohol 70% v/v	antiseptic

Use(s)
Hand sanitizer to help reduce bacteria that potentially can cause disease, for use when soap and water are not available.

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

When using this product
Do not use on open skin wounds.
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 the reach of children
Do not use in children less than 2 months of age.
If swallowed, get medical help or contact a Poison Center right away.

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

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

Inactive ingredients
Water, Carbomer homopolymer Type C, Glycerin, Triethanolamine.



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Manufactured by:
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Made in Mexico

Drug facts	NDC 78499-100-04
Active ingredients	purpose Ethyl alcohol 70% v/v..... antiseptic
Use(s)	Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.
Warnings	For external use only. Flammable. Keep away from heat or flame.
When using this product	Do not use on open skin wounds. 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	Do not use in children less than 2 months of age. If swallowed, get medical help or contact a Poison 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 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F)
Inactive ingredients	Water, Carbomer homopolymer type C, Glycerin, Triethanolamine.

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KTM POWER HAND

HAND SANITIZER



+VITAMIN E

NO RINSING

**70%
ALCOHOL**

135 FL OZ (4 LITERS)

KTM POWER HAND

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78499-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:78499-100-01	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/15/2020	
2	NDC:78499-100-04	4000 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/15/2020	
3	NDC:78499-100-05	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/23/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/15/2020	

Labeler - Regenera y Transforma, S.A. de C.V. (951577608)

Establishment

Name	Address	ID/FEI	Business Operations
Regenera y Transforma, S.A. de C.V.		951577608	manufacture(78499-100)

Revised: 6/2020

Regenera y Transforma, S.A. de C.V.