

**VANT36.5 SAFE CLEAN- alcohol gel**  
**Opseve KOREA Co.,Ltd.**

*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.*

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**ACTIVE INGREDIENT**

Active ingredients: ALCOHOL 70%

**INACTIVE INGREDIENT**

Inactive ingredients:

Water, Glycerin, Dipotassium Glycyrrhizate, Camellia Sinensis Leaf Extract, Aloe Barbadensis Leaf Juice Powder, Sodium Hyaluronate, DL-Panthenol, Tocopheryl Acetate, Carbomer, Aminomethyl Propanol

**PURPOSE**

Purpose: SANITIZER

**WARNINGS**

Warnings:

1.Do not use the product on the following areas:

Around the eyes and ears, in the mouth, large body parts and damaged skin(Irritation may occur)

2.If you experience any of the following symptoms, discontinue use of the product immediately and consult a physician or pharmacist.

1) Hypersensitivity symptoms, e.g. rash, erythema, itchiness, and edema

2)Skin irritation symptoms

3.Other precautions

1) For external use only (do not swallow).

2) Avoid contact with eyes. If contact occurs, wash with clean water and consult a doctor or pharmacist.

3)Be careful not to inhale vapors in cases of extended or prolonged use. (Repeating inhaling of large amounts of ethanol vapor may cause irritation of the mucous membranes and headaches).

(Limited to ethanol-containing products)

4) If used repeatedly in the same area, care should be provided as the skin may become rough due to excessive oil removal.

5) Do not use sealed bandages, cast bandages, or packs as they may cause irritation.

6) Do not use this drug on the anal or vagina areas, or with hot packs, as it may cause irritation or chemical burns.

7) Use only for the intended purposes.

4.Precautions for storage

1) Keep away from direct sunlight and do not expose the product to heating devices or flame.

2) Keep out of reach of children and go to the hospital immediately if swallowed.

3) After use, close the lid completely to prevent the product from drying or foreign objects from getting inside the container.

4) Storing the product in a different container may cause accidents or deterioration of quality.

Therefore, keep the product in its original container.

Dust or foreign substances may get on the product while using it.

**KEEP OUT OF REACH OF CHILDREN**

Keep out of reach of children and go to the hospital immediately if swallowed.

**Uses**

Uses:

Disinfection of hands and skin

**Directions**

Directions:

Take an appropriate amount on your hands and rub thoroughly to dry.

**PACKAGE LABEL - VANT36.5 SAFE CLEAN GEL 50mL**

  
**SAFE**  
Ethanol 70%

VANT36.5

## Drug Facts

**Active ingredients**

ALCOHOL 70%

**Purpose**  
SANITIZER

**Uses** Disinfection of hands and skin

**Warnings**

1. Do not use the product on the following areas: Around the eyes and ears, in the mouth, large body parts and damaged skin (Irritation may occur)  
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**Opseve KOREA Co.,Ltd.**

364 Seunggicheon-ro, Namdong-gu, Incheon, S. Korea

**Net Wt**

50mL / 1.69 Fl. Oz.



**PACKAGE LABEL - VANT36.5 SAFE CLEAN GEL 500mL**



Ethanol 70%

VANT36.5

Drug Facts

**Active ingredients**  
ALCOHOL 70%

**Purpose**  
SANITIZER

**Uses** Disinfection of hands and skin

**Warnings**

1. Do not use the product on the following areas: Around the eyes and ears, in the mouth, large body parts and damaged skin (Irritation may occur) 2. If you experience any of the following symptoms, discontinue use of the product immediately and consult a physician or pharmacist: 1) Hypersensitivity symptoms, e.g. rash, erythema, itching, and edema 2) Skin irritation symptoms 3. Other precautions 1) For external use only (do not swallow). 2) Avoid contact with eyes. If contact occurs, wash with clean water and consult a doctor or pharmacist. 3) Be careful not to inhale vapors in cases of extended or prolonged use. (Repeating inhaling of large amounts of ethanol vapor may cause irritation of the mucous membranes and headaches). (Limited to ethanol-containing products) 4) If used repeatedly in the same area, care should be provided as the skin may become rough due to excessive oil removal. 5) Do not use sealed bandages, cast bandages, or packs as they may cause irritation. 6) Do not use this drug on the anal or vagina areas, or with hot packs, as it may cause irritation or chemical burns. 7) Use only for the intended purposes. 4. Precautions for storage 1) Keep away from direct sunlight and do not expose the product to heating devices or flame. 2) Keep out of reach of children and go to the hospital immediately if swallowed. 3) After use, close the lid completely to prevent the product from drying or foreign objects from getting inside the container. 4) Storing the product in a different container may cause accidents or deterioration of quality. Therefore, keep the product in its original container. Dust or foreign substances may get on the product while using it.

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**Opseve KOREA Co., Ltd.**

364 Seunggicheon-ro, Namdong-gu, Incheon, S. Korea

**Net Wt**

500mL / 16.90 Fl. Oz.



**VANT36.5 SAFE CLEAN**

alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:74195-020
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Glycerin (UNII: PDC6A3C0OX)	
GLYCYRRHIZINATE DIPO TASSIUM (UNII: CA2Y0FE3FX)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
PANTHENOL (UNII: WV9CM0O67Z)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	

**Packaging**

#	Item Code	Package Description	Marketing Start	Marketing End Date
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#	Item Code	Package Description	Date	Marketing End Date
1	NDC:74195-020-01	50 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/01/2020	
2	NDC:74195-020-02	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	03/01/2020	

**Labeler** - Opseve KOREA Co.,Ltd. (690048629)

**Registrant** - Opseve KOREA Co.,Ltd. (690048629)

### Establishment

Name	Address	ID/FEI	Business Operations
Opseve KOREA Co.,Ltd.		690048629	manufacture(74195-020)

Revised: 4/2020

Opseve KOREA Co.,Ltd.