

SANIGEN- alcohol spray
WORLDICHEM 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.

ethanol (synthetic alcohol) 62%

Water, Carbomer, Triethanolamine, Glycerin, Tocopheryl Acetate, L-menthol, Lemon oil

- instant healthcare personnel hand antiseptic to reduce bacteria that potentially can cause disease
- instant hand antiseptic to decrease bacteria on the skin
- if following abnormal symptoms persist, discontinue use

Irritation around the eyes, ears, mucous membranes, including the mouth, under the skin irritation and rashes

- Stop immediately and consult a doctor if you experience

1) Hypersensitivity symptoms such as erythema, itching and dermatitis.

2) Skin Irritation

3) Following Instructions when using medication

(1) For external use only (Do not use internally)

(2) Avoid getting into the eyes (if contact occurs, wash well with clean water)

- Be careful not to inhale or use excessively for a long time (ingesting ethanol repeatedly causes irritation to mucous membranes and headaches or other symptoms may appear. When used repeatedly in the same area, skin irritation may occur.

- Do not use the product for a long time in the same area as swelling, inflammation or sickness may occur due to absorption through the skin.

It is not recommended to use this one areas that have been medically treated with a cast or bandage.

- Do not use in combination with soap or antibacterial cleansing agents.

• Keep Out of Reach of Children.

- spray a small amount into hands, spread evenly and rub into the skin

for topical use only

Sanigen spray / 50ml

Drug Facts

Active Ingredients

Ethanol (Synthetic Alcohol) 62% ----- Purpose Disinfecting Agent

Uses

- instant healthcare personnel hand antiseptic to reduce bacteria that potentially can cause disease
- instant hand antiseptic to decrease bacteria on the skin

Warning

For external use only

When using this product

- if following abnormal symptoms persist, discontinue use
Irritation around the eyes, ears, mucous membranes, including the mouth, under the skin irritation and rashes
- Stop immediately and consult a doctor if you experience
 - 1) Hypersensitivity symptoms such as erythema, itching and dermatitis.
 - 2) Skin Irritation
 - 3) Following Instructions when using medication
 - (1) For external use only (Do not use internally)
 - (2) Avoid getting into the eyes (if contact occurs, wash well with clean water)
- Be careful not to inhale or use excessively for a long time (ingesting ethanol repeatedly causes irritation to mucous membranes and headaches or other symptoms may appear. When used repeatedly in the same area, skin irritation may occur.
- Do not use the product for a long time in the same area as swelling, inflammation or sickness may occur due to absorption through the skin. It is not recommended to use this one areas that have been medically treated with a cast or bandage.
- Do not use in combination with soap or antibacterial cleansing agents.

Directions

- Spray a small amount into hands, spread evenly and rub into the skin

Other Information

- read the directions and warnings before use
- avoid freezing and excessive heat above 40 degree C (104 degree F)

Inactive Ingredients

Water, Glycerin, Tocopheryl Acetate, L-menthol, Lemon oil

alcohol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74538-0004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
LEVOMENTHOL (UNII: BZ1R15MTK7)	
GLYCERIN (UNII: PDC6A3C0OX)	
LEMON OIL (UNII: I9GRO824LL)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74538-0004-1	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/04/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/04/2020	

Labeler - WORLDCHEM CO LTD (631058864)

Registrant - WORLDCHEM CO LTD (631058864)

Establishment

Name	Address	ID/FEI	Business Operations
WORLDCHEM CO LTD		631058864	manufacture(74538-0004)

Revised: 5/2020

WORLDCHEM CO LTD