

SANITIZER HAND AND SKIN CARE- silver chloride cream Immunetec Proof Ltd.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Immunetec Hand Sanitizer

Active Ingredient

Silver Chloride 0.3% w/w

Purpose

Antiseptic

Uses

To help reduce the number of disease-causing bacteria, virus, and fungi until the next hand wash.

For use when soap and water are not available.

Warnings

For external use only.

Keep out of reach of children under 6 years of age.

When using this product:

- keep out of eyes, ears, and mouth.
- Do not ingest.
- In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs.

Directions

- Apply after cleansing and drying the skin surface on hand or elsewhere.
- Apply a generous amount and spread evenly to cover all surfaces.
- Can be applied regularly.

Other information or comments

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

Inactive Ingredients

Water (Aqua), Stearic acid, Glycerin, Sodium bentonite, Phenoxyethanol, Acrylate copolymer, Triethanolamine, Caprylyl glycol, Titanium dioxide

Principal Display Panel

Sanitizer Hand and Skin Care (50 mL), NDC: 81541-001-01

Outer Package (Box)



immunetec®

SANITIZER
Hand and Skin care



- ✓ Alcohol-free ✓ Moisturizes
- ✓ Dermatologically tested
- ✓ Long lasting protective layer
- ✓ Hypoallergenic

**ANTIMICROBIAL HAND AND SKIN CARE
SILVER-ION HAND SANITIZER CREAM**

**KILLS 99,9 % OF BACTERIA, VIRUSES
AND FUNGI***

UP TO 4-5 HOURS PROTECTION**

**IMMUNETEC ANTIMICROBIAL HAND
AND SKIN CARE (50 ml)**

*Effective disinfection treatment that works immediately to fight bacteria, fungus, and selected viruses (including H1N1, norovirus) with the slow and controlled release of silver-ion component that guarantees protection on the skin surface **for 4-5 hours or until the next hand wash or cleansing.

- Clinically proven more effective than alcohol based hand sanitizers.
- Long lasting effect.
- Does not contain nano substances.
- No harsh ingredients that can cause dry flaky skin.
- Non-absorbent.
- Lightweight moisturizer sets to a soft matte finish.

1,7 FL OZ (50ml)



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Hand and Skin care



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Drug Facts

Active Ingredients	Purpose
Silver Chloride 0.3% w/w.....	Antiseptic
Uses	
• Hand Sanitizer to help reduce the number of disease-causing bacteria, virus, and fungi until the next hand wash.	
• For use when soap and water are not available.	
Warnings	
• For external use only	
• Keep out of reach of children under 6 years of age.	
• When using this product keep out of eyes, ears, and mouth. Do not ingest. In case of contact with eyes, rinse eyes thoroughly with water.	
• Stop use and ask doctor if irritation or rash occurs.	
Directions	
• Apply after cleansing and drying the skin surface on hand or elsewhere.	
• Apply a generous amount and spread evenly to cover all surfaces.	
• Can be applied regularly.	
Other information or comments	
• Store between 15-30C (59-86F)	
• Avoid freezing and excessive heat above 40C (104F).	
Inactive Ingredients	
Water (Aqua), Stearic acid, Glycerin, Sodium Bentonite, Phenoxyethanol, Acrylate Copolymer, Trietanolamine, Caprylyl glycol, Titanium Dioxide	

MANUFACTURED BY
Immunetec Proof Ltd.,
Hrsz. 082/9, Péteri, Hungary, 2209

Made in EU. Date of production: see top of package. Store at room temperature.

ISO 22196:2011 | EN 14885
Product type: PT1 Human Health
(skin contact disinfectant)
National Public Health Centre (NPHC) Opinion
No: 54828-2/2019/JIF
NPHC Licence No: 24812-3/2020/JIF

Inner Package (Tube)



immunetec®

SANITIZER

Hand and Skin care



- ✓ Alcohol-free
- ✓ Moisturizes
- ✓ Dermatologically tested
- ✓ Long lasting protective layer
- ✓ Hypoallergenic

HOW TO USE: Apply after cleansing and drying the skin surface on hand or elsewhere. Apply a generous amount and spread evenly. Effective treatment that works immediately to fight bacteria, fungus, and selected viruses (including H1N1, norovirus) with the slow and controlled release of silver-ion component that guarantees protection on the skin surface for 4-5 hours or until the next hand wash or cleansing. For everyday use. Can be applied regularly.

INGREDIENTS: Aqua, Stearic acid, Glycerin, Sodium Bentonite, Phenoxyethanol, Acrylate Copolymer, Trietanolamine, Caprylyl glycol, **Titanium Dioxide + Silver Chloride 0.3% w/w**

Date of production: see top of package.
Store at room temperature.

Manufactured by **Immunetec Proof Ltd.**
Made in: EU.

www.immunetec.eu



SANITIZER HAND AND SKIN CARE

silver chloride cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81541-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SILVER CHLORIDE (UNII: MWB0804EO7) (SILVER CATION - UNII:57N7B0K90A)	SILVER CATION	0.3 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ACRYLIC ACID/DIMETHICONE METHACRYLATE/ETHYLHEXYL ACRYLATE COPOLYMER (UNII: E5024Y9FFQ)	
TROLAMINE (UNII: 9O3K93S3TK)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM BENTONITE (UNII: K1BPI94O04)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81541-001-01	1 in 1 BOX	02/10/2021	
1		50 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/10/2021	

Labeler - Immunetec Proof Ltd. (366839547)

Registrant - Immunetec Proof Kft. (366839547)

Establishment

Name	Address	ID/FEI	Business Operations
Immunetec Proof Kft.		366839547	manufacture(81541-001)

Establishment

Name	Address	ID/FEI	Business Operations
Kedo Eurocosmetics Kft.		427068692	manufacture(81541-001)

Revised: 2/2021

Immunetec Proof Ltd.