

SMARTSHIELD- antimicrobial ointment ointment
Global Health Solutions DBA Turn Therapeutics

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.

Certainty® SmartShield Antimicrobial Ointment

Drug Facts

Active Ingredient

Benzalkonium chloride (0.13% i/s*)

Purpose

Antiseptic

Uses

- Helps to reduce pathogens that potentially can cause infections.

Warnings

Do not ingest

Ask a doctor before use if you have Signs of an existing infection

When using this product

- Do not use in or near the eyes.
- Do not use if you have a history of allergy to any of the ingredients.
- Do not use concurrently with other products on the same application site.

Stop use and ask a doctor

- If condition worsens
- Symptoms persist for more than 7 days, or clear up and occur again within a few days.

Keep out of reach of children.

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

Directions

Adults and children 2 years and older:

Skin Application

- Gently clean the affected area.
- Apply a small amount 1-3 times daily.
- May be covered with a sterile bandage.

Nasal Application

- Gently clean the inside of both nostrils, including tip(s).
- Apply a small amount of ointment to a sterile swab and insert into the nostril.
- Rotate swab for 10-15 seconds to cover all surfaces.
- Repeat process for other nostril with a new, sterile swab.
- Do not blow nose.
- May be used up to 2-3 times per day.

Other Information

Avoid excessive heat.

Inactive ingredients

USP Petrolatum, Purified Water, PHMB (antimicrobial preservative)

Questions?

833-871-2100

*Patented liquid-in-oil technology. Percentage reflective of active ingredient in solution.

Certainty®

SmartShield

Antimicrobial Ointment

Enhanced Skin and Nasal Protection

Powered by Hexagen®

Distributed by

Carismatic Brands

Chatsworth, CA

Net wt. 30g

Documented Protection Against:

- MRSA
- Staphylococcus Aureus
- Candida Auris
- Human Coronavirus
- Candida Albicans
- Pseudomonas

Antiviral

Antibacterial

Antifungal

Petrolatum-based

Non-cytotoxic

Extended-wear

Be Safe.

Be Smart.

Be Certain.

Made in USA

CertaintyShield.com

Manufactured in the USA

by Turn Therapeutics

SKU: CNCAM-MUL

NDC: 69578-224-30

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Questions? 833-871-2100	

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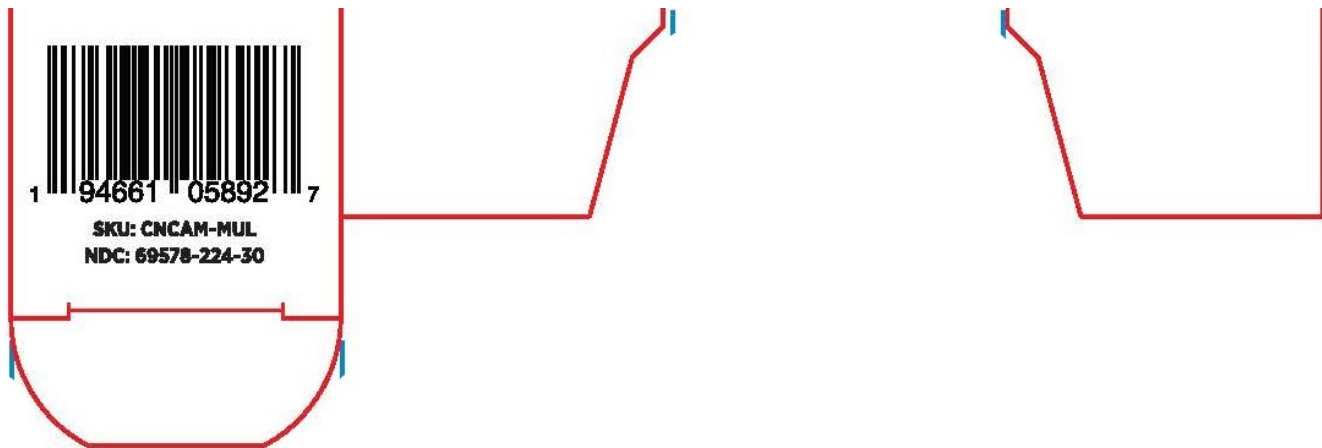
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SMARTSHIELD

antimicrobial ointment ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69578-224
Route of Administration	TOPICAL, NASAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
WATER (UNII: 059QF0K00R)	
POLYAMINO PROPYL BIGUANIDE (UNII: DT9D8Z79ET)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69578-224-30	30 g in 1 CARTON; Type 0: Not a Combination Product	10/04/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	10/04/2020	

Labeler - Global Health Solutions DBA Turn Therapeutics (079695890)

Registrant - Global Health Solutions DBA Turn Therapeutics (079695890)

Establishment

Name	Address	ID/FEI	Business Operations
Global Health Solutions DBA Turn Therapeutics		079695890	manufacture(69578-224) , label(69578-224)

Revised: 10/2020

Global Health Solutions DBA Turn Therapeutics