

SINOFRESH KOOLBLAST- sinofresh koolblast oral spray spray
ZapVir Inc.

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

SinoFresh KoolBlast Oral Antiseptic Spray

Active Ingredients

Mentha Piperita 3X

Purpose

Oral Antiseptic

Uses

- Kills germs and bacteria
- Reduces germs and bacteria in the mouth and throat

Warnings

Warnings

Ask a doctor before use if you have:

- had any medical procedures for the mouth or throat
- raw, scratchy or irritated throat

When using this product:

- do not spray in eyes. If contact occurs, rinse eyes with water
- do not share dispenser with others

Stop Use

Stop use and ask doctor if:

- condition persists for more than 7 days or worsens
- a rash or irritation occurs

Keep Our of Reach of Children

Keep out of reach of children.

If more than used for spraying is accidentally swallowed, get medical help or contact a Poison Control Center right away, 800-222-1222

Dosage and Administration

Directions

- Adults and children 12 years of age and older, 3 to 4 sprays in the throat, three times a day, or as needed
- Children under 12 years ask a doctor

Indications and Usage

Oral Antiseptic

- Reduces germs and bacteria in the mouth and throat

Inactive Ingredients

Inactive Ingredients: Aqua (water), benzalkonium chloride, cetylpyridinium chloride, edetate disodium, eucalyptus oil, glycerin, menthol, polysorbate 80, sorbitol, sucralose, xylitol

Warnings

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DRUG FACTS	
Active Ingredient	Purpose
Mentha piperita 3X	Oral Antiseptic
Uses	
<ul style="list-style-type: none"> • Kills germs and bacteria • Reduces germs and bacteria in the mouth and throat 	
Warnings	
Ask a doctor before use if you have:	
<ul style="list-style-type: none"> • had any medical procedures for the mouth or throat • raw, scratchy or irritated throat 	
When using this product:	
<ul style="list-style-type: none"> • do not spray in eyes. If contact occurs, rinse eyes with water • do not share dispenser with others 	
Stop use and ask doctor if:	
<ul style="list-style-type: none"> • condition persists for more than 7 days or worsens • a rash or irritation occurs 	
Keep out of reach of children.	
If more than used for spraying is accidentally swallowed, get medical help or contact a Poison Control Center right away, 800-222-1222	
Directions	
<ul style="list-style-type: none"> • Adults and children 12 years of age and older, 3 to 4 sprays in the throat, three times a day, or as needed • Children under 12 years ask a doctor 	
Other Information	
Store at room temperature and away from direct sunlight	
Inactive Ingredients	
Aqua (water), benzalkonium chloride, cetylpyridinium chloride, edetate disodium, eucalyptus oil, glycerin, menthol, polysorbate 80, sorbitol, sucralose, xylitol	
Questions?	888-460-4774
Tamper Evident Warning:	
Do not use if shrinkwrap around carton is torn or missing.	

SINOFRESH KOOLBLAST

sino fresh koolblast oral spray spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79961-003
Route of Administration	OROPHARYNGEAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHA PIPERITA (UNII: 79M2M2UDA9) (MENTHA PIPERITA - UNII:79M2M2UDA9)	MENTHA PIPERITA	0.1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength

SORBITOL (UNII: 506T60A25R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
MENTHOL (UNII: L7T10EIP3A)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
CETYLPIRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
WATER (UNII: 059QF0KO0R)	
XYLITOL (UNII: VCQ006KQ1E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79961-003-01	60 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	10/12/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		10/12/2020	

Labeler - ZapVir Inc. (117600850)

Registrant - ZapVir Inc. (117600850)

Establishment

Name	Address	ID/FEI	Business Operations
EMS Acquisition Corp		048602791	manufacture(79961-003)

Revised: 10/2020

ZapVir Inc.