SINOFRESH NASAL AND SINUS CARE- eucalyptus globulus leaf, potassium dichromate liquid
EMS Contract Packaging

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.

Recertify - EMS (as CMO) - SINOFRESH, NASAL (59228-103)

ACTIVE INGREDIENTS

EUCALYPTUS GLOBULUS 20X

KALIUM BICHROMICUM 30X

PURPOSE

ANTISEPTIC

RELIEVES SINUS PAIN, PRESSURE AND INFLAMMATION

USES

RELIEVES NASAL AND SINUS SYMPTOMS ASSOCIATED WITH PERSISTENT SINUS CONDITIONS:

- CONGESTION
- NASAL INFLAMMATION
- SINUS PRESSURE
- FACIAL PIN
- SINUS HEADACHE
- STUFFY NOSE

ASK A DOCTOR BEFORE USE IF YOU HAVE

- HAD ANY MEDICAL PROCEDURES FOR YOUR NOSE OR SINUSES
- A BLEEDING OR IRRITATED NOSE

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.

DIRECTIONS

- ADULTS AND CHILDREN 12 YEARS OF AGE AND OLDER (WITH ADULT SUPERVISION) MORNING AND EVENING, APPLY 1 TO 2 SPRAYS TO EACH NOSTRIL.

OTHER INGREDIENTS

BENZALKONIUM CHLORIDE, CETYLPYRIDINIUM CHLORIDE, DBASIC SODIUM PHOSPHATE, ESSENTIAL OIL BLEND (CONSISTING OF WINTERGREEN OIL, SPEARMINT OIL, PEPPERMINT OIL, AND EUCALYPTUS OIL), MONOBASIC SODIUM PHOSPHATE, POLYSORBATE 80, PROPYLENE GLYCOL, PURIFIED WATER, SODIUM CHLORIDE, AND SORBITOL SOLUTION


Antiseptic
SINO
FRESH
NASAL & SINUS CARE
HOMEOPATHIC NASAL SPRAY
Eases discomfort from:
• Congestion
• Sinus pain & pressure
• Sinus headache
1 FL. OZ. (29.6mL)
LBFNASAL2 REV3

Lift Here

Homeopathic
Antiseptic

NASAL & SINUS CARE

Distributed by
SinoFresh HealthCare, Inc.
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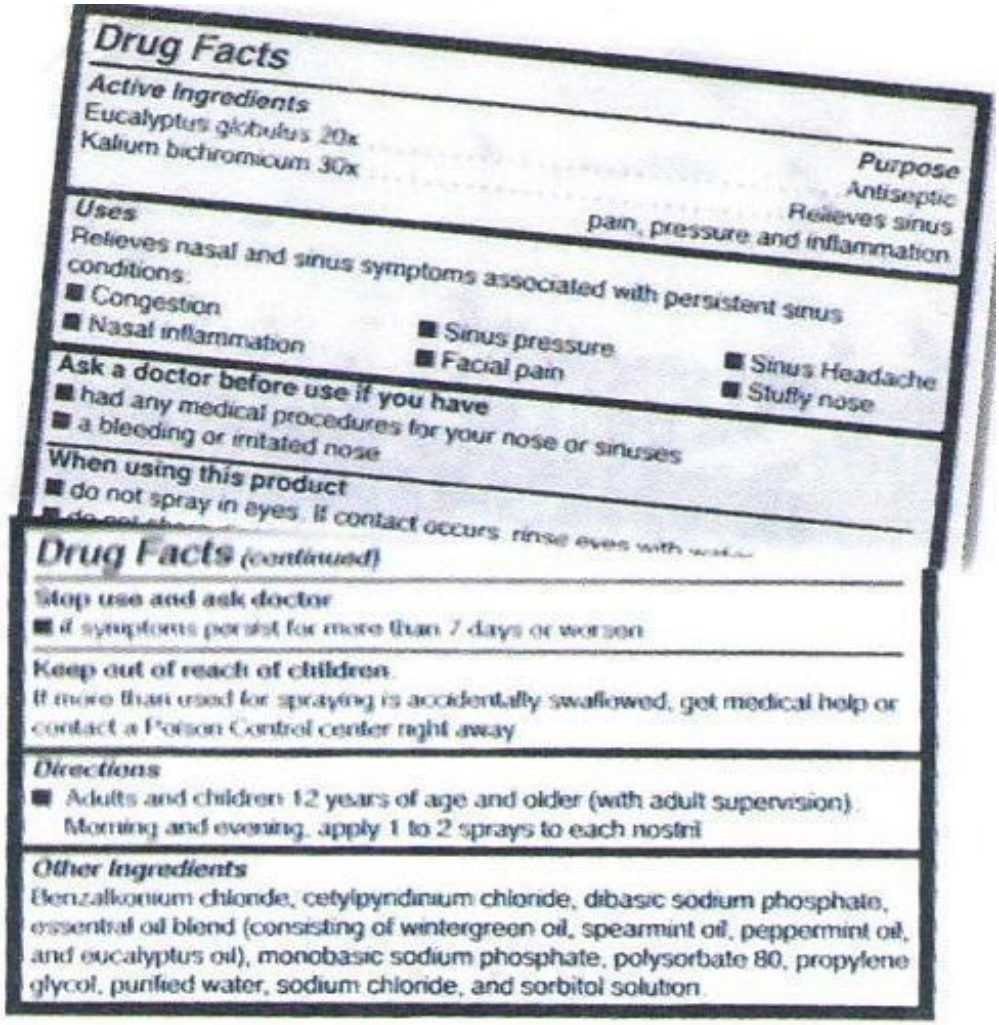
Patent Numbers:
5,785,988; 6,083,525; 6,344,210
and other US and foreign patents pending

LBBNASAL2 REV2



Drug Facts

Active Ingredients
Eucalyptus globulus 20x
Kalium bichromicum 30x

Purpose
Antiseptic
Relieves sinus pain, pressure and inflammation

Uses
Relieves nasal and sinus symptoms associated with persistent sinus conditions:
- Congestion
- Nasal inflammation
- Sinus pressure
- Facial pain
- Sinus Headache
- Stuffy nose

Ask a doctor before use if you have
- had any medical procedures for your nose or sinuses
- a bleeding or irritated nose

When using this product
- do not spray in eyes. If contact occurs, rinse eyes with water

Drug Facts (continued)

Stop use and ask doctor
- if symptoms persist for more than 7 days or worsen

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

Directions
- Adults and children 12 years of age and older (with adult supervision): Morning and evening, apply 1 to 2 sprays to each nostril

Other Ingredients
Benzalkonium chloride, cetylpyridinium chloride, dibasic sodium phosphate, essential oil blend (consisting of wintergreen oil, spearmint oil, peppermint oil, and eucalyptus oil), monobasic sodium phosphate, polysorbate 80, propylene glycol, purified water, sodium chloride, and sorbitol solution.

SINOFRESH NASAL AND SINUS CARE

eucalyptus globulus leaf, potassium dichromate liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59228-103
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6) (EUCALYPTUS GLOBULUS LEAF - UNII:S546YLW6E6)	EUCALYPTUS GLOBULUS LEAF	20 [hp_X] in 100 mL
POTASSIUM DICHROMATE (UNII: T4423S18FM) (DICHROMATE ION - UNII:9LKY4BFN2V)	POTASSIUM DICHROMATE	30 [hp_X] in 100 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	

SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
SPEARMINT OIL (UNII: C3M81465G5)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SORBITOL (UNII: 506T60A25R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59228-103-11	29.6 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/30/2014	

Labeler - EMS Contract Packaging (048602791)

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