

SINUSIN - pulsatilla vulgaris and euphorbia resinifera resin and luffa opsilver nitrateerculata fruit and mercuric iodide and sus scrofa nasal mucosa and silver nitrate and calcium sulfide and sinusitisinum solution

Biologische Heilmittel Heel

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.

DOSAGE FORM

Oral liquid in vials.

CONTRAINDICATIONS

This drug is contraindicated in patients with a known hypersensitivity to any of its ingredients.

PRECAUTIONS

Pregnancy and nursing mothers: Pregnancy Category C. In general, homeopathic drugs are not known to cause direct or indirect harm to the fetus. However, animal reproduction studies have not been performed and there are no well-controlled studies in pregnant women. In cases of pregnancy or suspected pregnancy, a physician should be consulted before administering this drug. It is not known whether any of the ingredients are excreted in human milk. However because many drugs are excreted in human milk, homeopathic drugs should be administered with caution to nursing mothers.

Pediatric use: Homeopathic drugs can be safely administered to children. See Dosage and Administration.

ADVERSE REACTIONS

In rare cases, patients with a hypersensitivity to any of the ingredients may experience an allergic reaction after oral administration.

DRUG ABUSE AND DEPENDENCE

Not applicable for homeopathic drugs.

OVERDOSAGE

Due to the low concentration of active ingredients, adverse reactions following overdosage are extremely rare. Care must be taken not to exceed the recommended dosage.

WARNINGS

If symptoms persist for more than a few days, a physician should be consulted.

Keep this and all medicines out of the reach of children.

HOW SUPPLIED

Heel vials are supplied in sizes of 1.1ml, 2.0ml and 2.2ml. See carton label for content information.

STORAGE CONDITION

Avoid freezing and excessive heat. Store at room temperature. Protect from direct light.

DOSAGE AND ADMINISTRATION

Adults and children above 6 years: In general 1 vial 1-3 times daily

Children to 6 years: 1/2 the adult dosage

Administration: NOT FOR INJECTION - FOR ORAL ADMINISTRATION ONLY.

Instructions for Opening Vial

1. Vials are pre-scored for easy opening and are marled with a color dot above the neck of the vial. The use of a file is not required. First, ensure that all contents of the vial are below the narrow neck by gently flicking or tapping top of the vial with fingers as in Step (1).



2. Hold vial firmly with one hand with dot toward you (2).



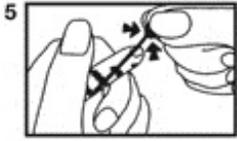
3. With the other hand, snap the vial top slightly upward and away from dot (3). Discard the vial top and be careful of sharp glass edges.



4. To withdraw solution: Tilt open vial until it is nearly horizontal (The vial should be tilted as far as possible without spilling the contents.) (4).



5. Squeeze bulb of the pipette and insert pipette tip into the solution (5).



6. Slowly release pressure on the bulb of the pipette until solution is withdrawn from vial (6).



7. Remove pipette when the solution has been withdrawn (7).



Administer according to carton insert. Discard unused portion.

BE CAREFUL OF SHARP EDGES AFTER OPENING VIAL.

NDC 50114-5347-6

SINUSINTM

INDICATIONS: For the temporary relief of:

- Nasal congestion
- Runny nose
- Rhinitis and Sinusitis
- Dry nasal membranes
- Cold and flu symptoms

CONTENTS: 10 oral vials of 2.2 ml each

Ingredients: Each vial contains: Pulsatilla 2X, Euphorbium officinarum 4X, Luffa operculata 6X, Mercurius iodatus ruber 8X, Mucosa nasalis suis 8X, Argentum nitricum 10X, Hepar sulphuris calcareum 10X, Sinusitusinum 13X .022 ml each in an isotonic sodium chloride solution base.

Inactive Ingredient: Isotonic sodium chloride solution.

To Open: Snap top up and away from colored dot.

NOT FOR INJECTION

-Heel[®]



Lot #

Exp.

SINUSIN

pulsatilla vulgaris and euphorbia resinifera resin and luffa operculata fruit and mercuric iodide and sus
scrofa nasal mucosa and silver nitrate and calcium sulfide and sinusitisinum solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51885-3150
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PULSATILLA VULGARIS (UNII: I76KB35JEV) (PULSATILLA VULGARIS - UNII:I76KB35JEV)	PULSATILLA VULGARIS	2 [hp_X] in 2.2 mL
EUPHORBIA RESINIFERA RESIN (UNII: 1TI1O9028K) (EUPHORBIA RESINIFERA RESIN - UNII:1TI1O9028K)	EUPHORBIA RESINIFERA RESIN	4 [hp_X] in 2.2 mL
LUFFA OPERCULATA FRUIT (UNII: C4MO6809HU) (LUFFA OPERCULATA FRUIT - UNII:C4MO6809HU)	LUFFA OPERCULATA FRUIT	6 [hp_X] in 2.2 mL
MERCURIC IODIDE (UNII: R03O05RB0P) (MERCURIC IODIDE - UNII:R03O05RB0P)	MERCURIC IODIDE	8 [hp_X] in 2.2 mL
SUS SCROFA NASAL MUCOSA (UNII: ID3Z1X61WY) (SUS SCROFA NASAL MUCOSA - UNII:ID3Z1X61WY)	SUS SCROFA NASAL MUCOSA	8 [hp_X] in 2.2 mL
SILVER NITRATE (UNII: 95IT3W8JZE) (SILVER CATION - UNII:57N7B0K90A)	SILVER NITRATE	10 [hp_X] in 2.2 mL
CALCIUM SULFIDE (UNII: 1MBW07J51Q) (SULFATE ION - UNII:7IS9N8KPMG)	CALCIUM SULFIDE	10 [hp_X] in 2.2 mL
SINUSITISINUM (UNII: B575563DM5) (SINUSITISINUM - UNII:B575563DM5)	SINUSITISINUM	13 [hp_X] in 2.2 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51885-3150-1	2.2 mL in 1 VIAL, GLASS		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		01/01/2011	

Labeler - Biologische Heilmittel Heel (315635359)