

SINUCLEAN - ecballium elaterium solution spray
Galsor S.r.l

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.

Ecballium Elaterium extract

PURPOSE

Helps expel mucus from the paranasal sinuses.

Helps reduce symptoms of sinusitis (headache, facial pain, heavy head, nasal obstruction, malaise).

USES

- Reduces intensity and duration of sinusitis symptoms.
- Helps expel mucus from the paranasal sinuses.
- Facilitates recovery sinusitis attack.

WARNING

Stop use and ask a doctor in case symptoms persist and are accompanied by fever.

Contains no antibacterial, anti-allergic or anti-flu activity.

If you are pregnant or breast-feeding, consult a doctor before use.

Do not use in children under 6 years old.

Keep out of reach of children.

Do not use if you are allergic to one of the ingredients or the product.

DIRECTIONS

In erect position, gently insert the nozzle into each nostril, the spray 2 to 3 puffs. Repeat 2 times/day, for 3-6 days. In case of excessive sneezing after the first spray puff, repeat the treatment after 15 minutes, as the product could have been wiped away mechanically by the sneezing.,

Do not expose the product to the light or heat. Take care to close the bottle after the use.

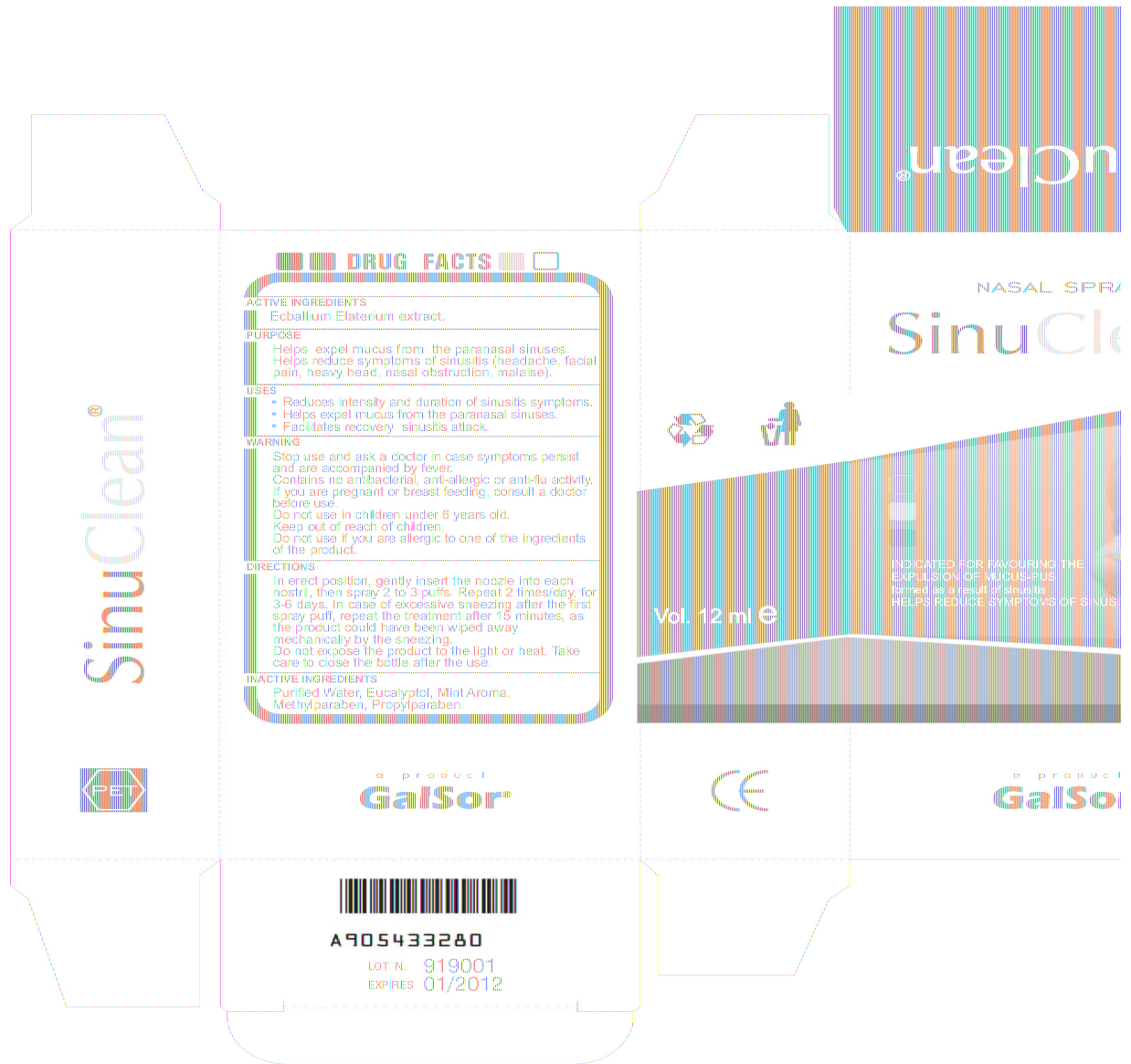
Purified Water, Eucalyptol, Mint Aroma, Methylparaben, Propylparaben

This section contains images of the bottle and carton labels.

This is the bottle label.



This is the carton label.



SINUCLEAN

ecballium elaterium solution spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:47784-001
Route of Administration	NASAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ECBALLIUM ELATERIUM FRUIT (UNII: 8P8HWT6ZWC) (ECBALLIUM ELATERIUM FRUIT - UNII:8P8HWT6ZWC)	ECBALLIUM ELATERIUM FRUIT	22.09 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
EUCALYPTOL (UNII: RV6J6604TK)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47784-001-01	1 in 1 CARTON		
1		12 mL in 1 BOTTLE, SPRAY		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		10/22/2009	

Labeler - Galsor S.r.l (338738618)

Revised: 10/2009

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