

COMPANY ANNOUNCEMENT

Green Pharmaceuticals Inc Issues Voluntary Nationwide Recall of SnoreStop NasoSpray Due to Microbial Contamination

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

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Summary

Company Announcement Date:

June 09, 2022

FDA Publish Date:

June 09, 2022

Product Type:

Drugs

Reason for Announcement:

Due to microbial contamination identified as *Providencia rettgeri*.

Company Name:

Green Pharmaceuticals Inc

Brand Name:

SnoreStop

Product Description:

Nasal spray

Company Announcement

FOR IMMEDIATE RELEASE – June 09, 2022 – Camarillo, California, Green Pharmaceuticals Inc is voluntarily recalling lot 2373/21222 of SnoreStop NasoSpray, packaged in 0.3 FL OZ (9ml) bottles to the consumer level. FDA testing found product to contain microbial contamination identified as *Providencia rettgeri*.

This microorganism is rarely associated with human illness; however, in immunocompromised patients, the use of the recalled product could potentially result in severe or life-threatening adverse events such as bacteremia/sepsis, pneumonia, invasive fungal rhinosinusitis, or disseminated fungal infection. In non-immunocompromised patients, the use of the recalled product may result in infectious complications that are expected to be less severe and more readily responsive to treatment. To date, Green Pharmaceuticals Inc has not received any reports of adverse events related to this recalled lot.

The product is used as a nasal spray to temporarily help stop or reduce symptoms of non-apneic snoring and is packaged in one single unit plastic bottle with a nasal pump as a delivery system. The affected SnoreStop NasoSpray lot include the following: 2372/21222 (2373 is printed on a sticker placed on the bottom of the bottle and 21222 is on a sticker placed on the outer packaging). The product can be identified by a clear transparent plastic box with the name SnoreStop NasoSpray. The product was distributed nationwide in health food stores and online.

Green Pharmaceuticals Inc is notifying its retailers and customers by email and is arranging for return and replacement of all recalled products. Consumers and retailers that have product which is being recalled should stop using and return to place of purchase.

Consumers with questions regarding this recall can contact Green Pharmaceuticals Inc by phone at 805-388-0600 or e-mail address (mail@snorestop.com (<mailto:mail@snorestop.com>)), Monday through Friday, 8 AM to 5 PM Pacific Standard Time. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online:** [www.fda.gov/medwatch/report.htm \(/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda\)](http://www.fda.gov/medwatch/report.htm (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda))
- **Regular Mail or Fax:** Download form [www.fda.gov/MedWatch/getforms.htm \(/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting\)](http://www.fda.gov/MedWatch/getforms.htm (/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting)) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Company Contact Information

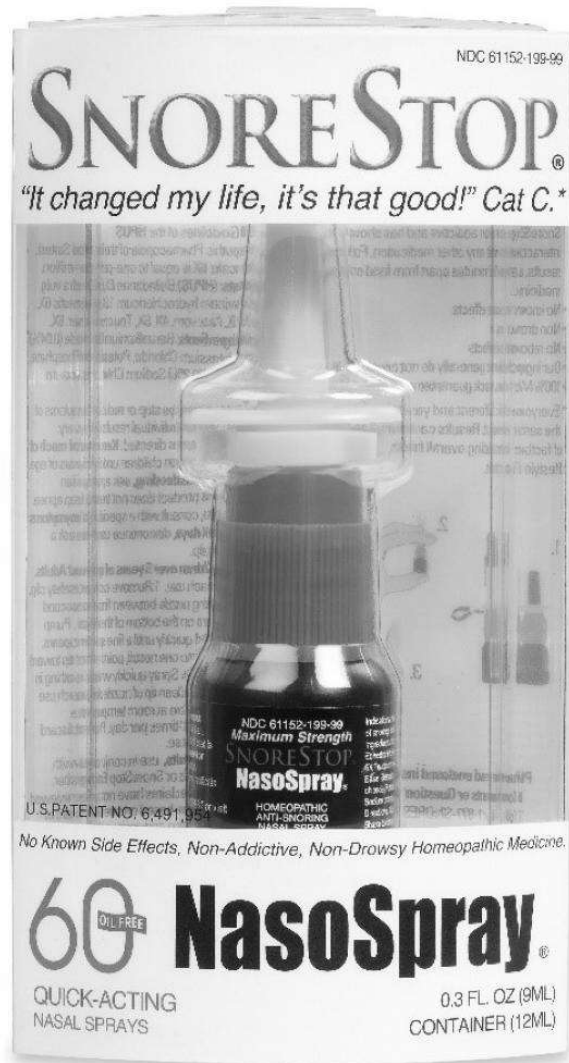
Consumers:

Green Pharmaceuticals Inc

☎ 805-388-0600

✉ mail@snorestop.com (<mailto:mail@snorestop.com>)

Product Photos



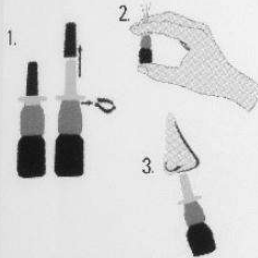
SNORESTOP
 keeping you together.TM
SNORESTOP NasoSpray[®]

Formulated by a Naturopathic Doctor.

SnoreStop is non-addictive and has shown no drug interaction with any other medication. For best results, use 15 minutes apart from food or any other medicine.

- No known side effects
- No drowsy
- No rebound effects
- Our ingredients generally do not contain gluten
- 100% Money back guarantee with proof of purchase

*Everyone is different and you may not experience the same result. Results can depend on a variety of factors including overall health, diet, and other lifestyle factors.



Please read enclosed insert.
 Comments or Questions?
 Toll-free 1-877-SNOREST
 email: mail@snorestop.com
 Visit: www.snorestop.com

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 Pharmaceuticals,
 The Snoring Specialists[®]
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 Camarillo, CA 93012

Homeopathic OTC Drug Facts

This homeopathic medicine is safe and follows the FDA Guidelines of the **HPUS**

(Homeopathic Pharmacopeia of the United States). Dilution scale: 6X is equal to one-part-per-million.

Ingredients: (HPUS) Belladonna 6X, Euphrasia 6X, Histaminum hydrochloricum 12X, Hecystes 6X, Kali bic. 6X, Nux vom. 4X, 6X, Teucrium mar. 6X.

Inactive Ingredients: Benzalkonium Chloride (0.02%), Glycerin, Potassium Chloride, Potassium Phosphate, Purified water (98.2%), Sodium Chloride, Sodium Phosphate.

Uses: Temporarily helps stop or reduce symptoms of non-apneic snoring. Individual results may vary.

Warnings: Use only as directed. **Keep out of reach of children.** Do not use on children under 5 years of age.

If pregnant or breastfeeding, ask a physician before use. This product does not treat sleep apnea. For sleep apnea, consult with a specialist. **If symptoms worsen after 14 days,** discontinue use and ask a physician for help.

Directions: Children over 5 years of age and Adults.

Shake before each use. 1. Remove cap and safety clip.

2. Prime by placing nozzle between first and second finger with thumb on the bottom of the base. Pump sprayer firmly and quickly until a fine spray appears.

3. Insert spray tip into one nostril, pointing the tip toward the back of the nose. Spray quickly while breathing in through your nose. Clean tip of nozzle after each use and replace cap. Store at room temperature.

May be used up to 4 times per day. Please discard 6 months after first use.

For Maximum Results, use in conjunction with SnoreStop Fast Tabs or SnoreStop Extinguisher.

Disclaimer: These claims have not been reviewed by the FDA. They are based on over 200 years of homeopathic practice and various Materia Medica references.

TAMPER EVIDENT:

Use only if tamper resistant seal around the bottle is unbroken

THIS PRODUCT HAS NO EXPIRATION DATE.



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