

Padagis - Recall of nitroglycerin lingual spray

- On December 27, 2021, <u>Padagis announced</u> a consumer level recall of three lots of <u>nitroglycerin</u> lingual spray because of possible failure of the product to properly dispense medication; some units may contain a disassembled pump, affecting the ability to dispense medication.
- There is a remote risk that the product may not properly dispense medication to patients in the event of a malfunction of their dispensing unit. This recall applies only to the 12 g spray bottle and not the 4.9 g spray bottle of this medication.
 - Other nitroglycerin lingual products that are not being recalled are available for patients to use.

Product Description	NDC	Lot # (Expiration Date)
Nitroglycerin lingual spray, 400		150892 (10/2022);
mcg/spray, 200 metered	45802-210-02	153199 (2/2023);
sprays, 12 g bottle		156041 (4/2023)

- Nitroglycerin lingual spray is indicated for acute relief of an attack or prophylaxis of angina pectoris due to coronary artery disease.
- Per Padagis, if nitroglycerin lingual spray does not deliver the appropriate amount of nitroglycerin, the patient will likely continue to experience chest pain. The nitroglycerin lingual spray label advises that if relief is not obtained after 3 doses over 15 minutes the patient should promptly seek medical attention.
- To date, Padagis has not received any reports of adverse events related to this recall.
- Patients should seek immediate medical attention if they have experienced any problems that may be related to using the recalled nitroglycerin lingual spray.
- Patients who have the recalled nitroglycerin lingual spray injection should not use the recalled product, contact their pharmacy for a replacement, and return the product to their pharmacy.
- Contact Sedgwick/Stericycle by phone at 1-888-266-7912 or by email at padagis5665@sedgwick.com for more information about the recall.



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