

## Frequently Asked Questions - NARCAN® (naloxone HCl) Nasal Spray

1. What changed between the original NARCAN® (naloxone HCl) Nasal Spray and the new look NARCAN® Nasal Spray?

NARCAN® Nasal Spray device now has a red plunger for easy identification.

In addition, temperature excursions and storage conditions have been updated:

- Store at room temperature 68°F to 77°F (20°C to 25°C)
- Excursions permitted between 41°F to 104°F (5°C to 40°C)
- Do not freeze or expose to excessive heat above 104°F (40°C)
- Protect from light

NARCAN® Nasal Spray freezes at temperatures below 5°F (-15°C). If this happens, the device will not spray. If NARCAN® Nasal Spray is frozen and is needed in an emergency, do NOT wait for NARCAN® Nasal Spray to thaw. Get emergency medical help right away. However, NARCAN® Nasal Spray may be thawed by allowing it to sit at room temperature for 15 minutes, and it may still be used if it has been thawed after being previously frozen.

2. In the storage conditions, why did the low-end of the temperature range change from 59°F to 68°F?

This was a specific request from the FDA during review, in order to standardize the reference interval for room temperature. The agency set this by providing this language.

3. How long can the product be in the allowable excursion range up to 104°F (40°C) before affecting stability?

NARCAN® Nasal Spray has been tested and remains stable when placed in non-standard conditions up to 104°F (40°C) for up to 12 months.

4. How long can the product be in the allowable excursion range down to 41°F (5°C) before affecting stability? NARCAN® Nasal Spray has been tested and remains stable when placed in non-standard conditions down to 41°F (5°C) for up to 12 months.

5. How can a person know/tell if the product is frozen?

There is no visible way to tell if the contents are frozen without attempting to depress the plunger. If the product is frozen, the device will not spray. The red plunger will not move upwards as the frozen liquid contents are solidified.

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6. **How many times can the product be frozen and thawed before stability is affected?**

A freeze/thaw study was completed for NARCAN® Nasal Spray, per FDA guidelines, which included the completion of 10 freeze/thaw cycles within 28 days, with the longest frozen state period being 72 hours. No product degradation resulted during this study period.

7. **Are the ingredients and formulation the same?**

The ingredients are the exact same. The quantity (%) of one excipient (an inactive ingredient) has changed, which allows for greater stability.

8. **Can NARCAN® Nasal Spray be frozen/thawed?**

NARCAN® Nasal Spray cannot be used while in a frozen state, however if this occurs, refer to thawing instructions within the storage conditions section of the full Prescribing Information.

9. **Can customers “trade in/swap out” existing NARCAN® Nasal Spray for new look NARCAN® Nasal Spray with red plunger?**

No, returns will not be permitted for this purpose. Please refer to our Return Goods Policy.

10. **Is the price the same for NARCAN® Nasal Spray with new look?**

Yes, pricing for NARCAN® Nasal Spray remains the same, which has not changed since 2015. Public Interest price is \$75/carton (2 doses) and our WAC is \$125/carton (2 doses).

11. **Is the NDC number the same?**

Yes, the NDC number is the same.

12. **When will product change take place?**

We anticipate shipments to begin arriving Summer 2020.

13. **Is there any interruption to distribution?**

There will be no disruption to distribution.

14. **Has the manufacturing process changed?**

No, this process has not changed. The same manufacturing site, process, and equipment (compounding, filling, assembly and packaging) remain in place.

15. **Is the shelf-life the same?**

The shelf life is 24-months.

Please see full Prescribing information [\[enclosed/link\]](#).