



INSTRUCTIONS FOR USE

Trudhesa™ (true-deh-sa)

(dihydroergotamine mesylate)
nasal spray
For Nasal Use Only



622344

Remove and Follow When Dosing

This Instructions for Use contains
information on how to deliver Trudhesa.

Introduction

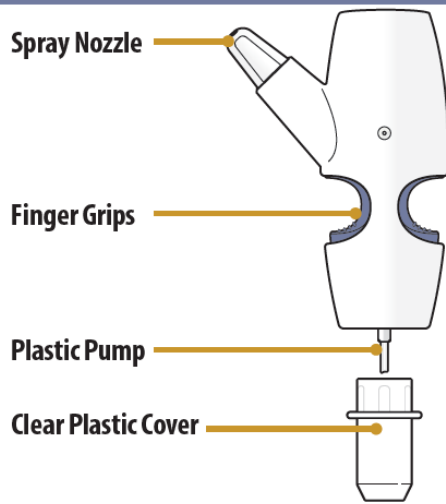
Read this Instructions for Use before you start to use Trudhesa and each time you get a prescription refill. There may be new information.

This information does not take the place of talking with your healthcare provider about your medical condition or treatment. You and your healthcare provider should talk about Trudhesa when you start taking it and at regular checkups.

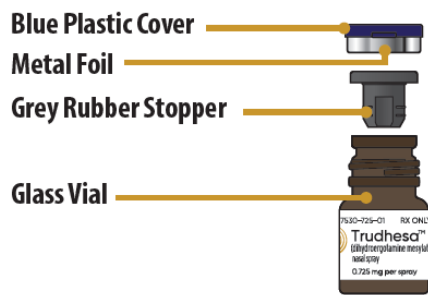
It is important to follow these directions accurately in order to receive the correct dose. Contact your healthcare provider if you have any questions about how to use this product.



Nasal Spray Device Parts



Glass Vial Parts



Important Information You Need To Know Before Dosing with Trudhesa

- For nasal use only.
- Always prime the nasal spray device before dosing by pumping the finger grips and glass vial together **exactly 4 times**.
- The purpose of priming is to bring the medicine to the tip of the spray nozzle. You may or may not see liquid or spray come out of the nozzle during each priming action.
- During priming, make sure to aim the spray nozzle away from your face and anything that you do not want coming into contact with the spray of medicine.
- A complete dose is 2 sprays; 1 spray in each nostril.
- **Do not** take more than 2 doses within a 24-hour period. **Do not** take more than 3 doses in a 7-day period.
- Always hold the nasal spray device perfectly upright when priming and when dosing.
- Sniffing while dosing is not necessary. However, sniffing will not hurt you nor make the medicine less effective.
- This nasal spray device product is single-dose (for one complete dose only) and should be thrown away (discarded) after use. You will need a new kit for each dose.
- Keep the product in the case until ready to use.
- After a TRUDHESA vial has been opened, it must be thrown away after 8 hours.
- **Do not** open the glass vial and expose to air until ready to use.
- Store at room temperature in a clean, dry area.
- **Do not** use if product is damaged.
- **Do not** use if product is expired.
- Each glass vial and nasal spray device can only be used 1 time. Throw away the entire nasal spray device after dosing, without removing the glass vial.
- You can take another complete dose at least 1 hour after your first dose if your symptoms persist.

Storing Trudhesa

- Store Trudhesa at room temperature between 68 °F to 77°F (20 °C to 25°C).
- Store Trudhesa in the original packaging in a clean, dry area away from heat and light (Figure A).
- Keep Trudhesa in the original packaging until you are ready to use.
- **Do not** refrigerate or freeze Trudhesa.
- **Keep Trudhesa and all medicines out of the reach of children.**

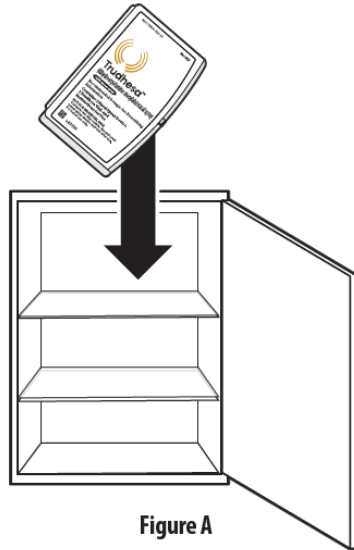


Figure A

Preparing to Dose with Trudhesa

Step 1: Gather and Check Supplies

1.1 Check to make sure you are using the right medicine for your migraine (see Figure B).

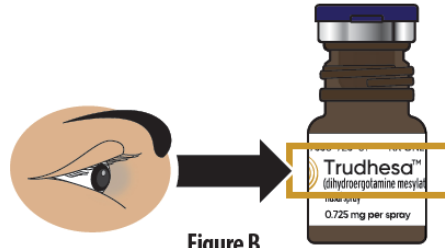


Figure B

1.2 Check to make sure Trudhesa is not expired (EXP) (see Figure C).

- If expired, throw away and get a new glass vial.

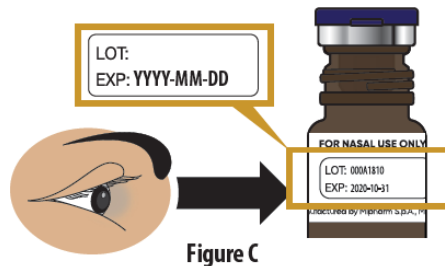


Figure C

1.3 Check to make sure that the glass vial and blue plastic cover do not look damaged.

Step 2: Remove Blue Plastic Cover, Metal Foil and Grey Rubber Stopper from Glass Vial

- 2.1 Remove (flip up) the blue plastic cover from the glass vial (see Figure D).
- 2.2 Use the blue plastic cover to slowly peel away all the metal foil from the grey rubber stopper in a circular motion (see Figure E).
- NOTE:** The metal foil may come off in 2 or more pieces. Make sure to remove all of the metal foil.

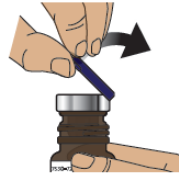


Figure D



Figure E

- 2.3 Pull the grey rubber stopper up and out of the glass vial (Figure F and Figure G).

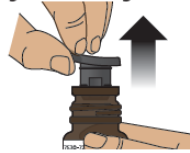


Figure F



Figure G

- 2.4 Throw away (discard) cover, foil and grey rubber stopper into the trash.

Step 3: Remove the Clear Plastic Cover from the Nasal Spray Device

- 3.1 Hold the nasal spray device upright.
 - 3.2 Pull down on the clear plastic cover and remove it from the nasal spray device (Figure H).
- Throw away the clear plastic cover.

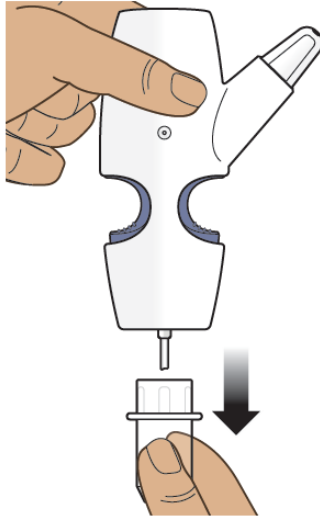


Figure H

Step 4: Screw the Glass Vial into the Nasal Spray Device

4.1 Hold the nasal spray device upright.

4.2 Gently push glass vial into the bottom of the nasal spray device (see Figure I) and screw it on until it is secured as shown in Figure J.

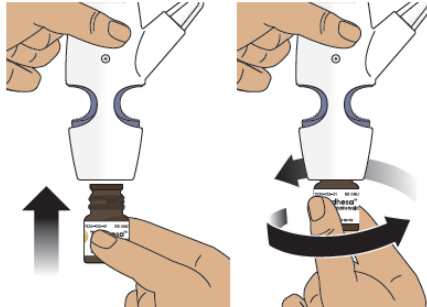


Figure I

Figure J

Step 5: Prime the Nasal Spray Device by Pumping Four Times with Fingers and Thumb

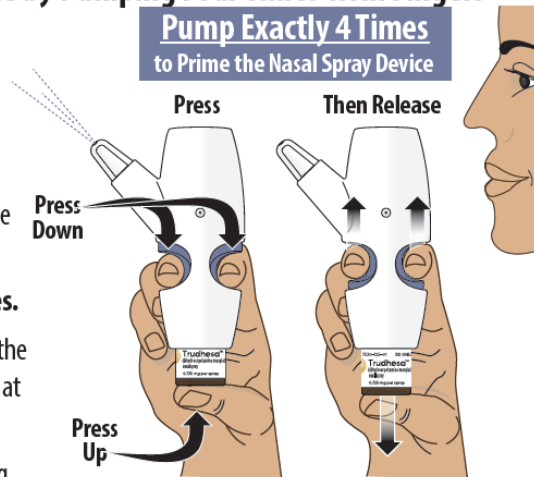
5.1 Hold the nasal spray device **upright**.

5.2 Point the spray nozzle away from your face.

5.3 Place your thumb on the bottom of the glass vial and place your pointer (index) and middle fingers on the finger grips (see Figure K).

5.4 Pump the nasal spray device **exactly 4 times**.

- To pump the nasal spray device, firmly press the finger grips down and press the glass vial up at the same time. Then release (see Figure K).
- You may see some medicine spray out during priming. This is normal. It is okay if you do not see medicine spray out on the first few pumps.



You may or may not see liquid each time you pump. Only pump 4 times to prime.

Figure K

Important Tip: The purpose of priming is to bring the medicine to the tip of the spray nozzle. If you do not prime the nasal spray device, you will not get your correct dose of medicine.

Always prime the nasal spray device before use by pumping **exactly 4 times**.

During priming, make sure to aim the nozzle away from your face and anything that you do not want coming into contact with the spray of medicine.

Using Trudhesa

Step 6: Position the Nasal Spray Device

- 6.1 Turn or re-grip the nasal spray device so that the spray nozzle faces you.
- 6.2 Make sure your head is straight and the nasal spray device is upright.
- 6.3 Insert the spray nozzle into your first nostril as far as comfortable (see Figure L).

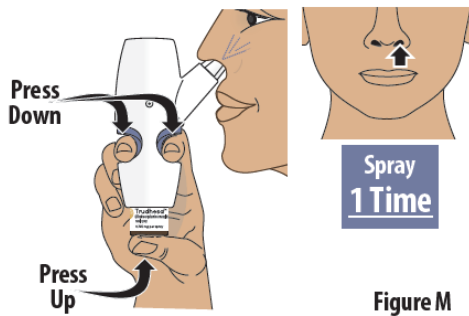


Figure L

Step 7: Spray the First Spray into 1 Nostril

7.1 Firmly press the finger grips down and press the glass vial up at the same time to deliver the first spray (see Figure M). Then release.

- Only deliver 1 spray into this nostril.

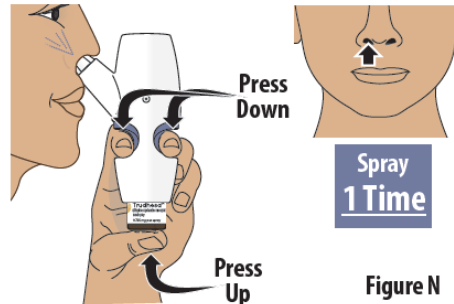


Step 8: Spray the Second Spray into Other Nostril

8.1 Move the spray nozzle into your other nostril.

8.2 Firmly press the finger grips down and press the glass vial up at the same time to deliver the second spray (see Figure N). Then release.

- Only deliver 1 spray into this nostril.



Important Tip: A complete dose is 2 sprays; 1 spray in each nostril.

Do not take more than 2 doses within a 24-hour period. **Do not** take more than 3 doses in a 7-day period. Please refer to the prescribing information for more information.

Sniffing while or after dosing is not necessary. However, sniffing will not hurt you or make the medicine less effective.

Important Frequently Asked Questions (FAQs)

Question: Can I save medicine by skipping the 4 pumps in “Step 5: Prime the Nasal Spray Device”?

Answer: No. Skipping the 4 pumps to prime the nasal spray device can result in you not getting your correct dose of medicine.

Question: When I first pumped the nasal spray device to prime nothing seemed to happen. Why?

Answer: The purpose of priming is to bring the medicine up to the tip of the nozzle. Even though you may not see or hear anything on your first pump or two, the pumping action will move the medicine from the glass vial through the inside of the nasal spray device and into the nozzle. You should see a spray by your fourth pump attempt. Always prime by pumping exactly 4 times prior to dosing.

Question: Can I reuse the nasal spray device with a new glass vial?

Answer: No. The nasal spray device is for one-time use only and must be thrown away after you have dosed (1 spray in each nostril). This is because the device may clog. After dosing, leave the glass vial screwed onto the nasal spray device and throw away the assembled nasal spray device into the trash. Do not recycle any part of the product.

Question: Can I use the medicine that remains in the glass vial for a later dose?

Answer: No. Although it is normal for some medicine to remain in the glass vial, it can not be used for later dosing. Any leftover medicine will become ineffective.

Question: What happens if I spray more than one time in the same nostril?

Answer: A complete and correct dose is one spray into each nostril. Do not dose in your other nostril if you already sprayed two times in one nostril. Talk to your healthcare provider if you have moderate to severe irritation in your nose or changes in smell.

Question: How soon can I take another dose if I am not getting relief from my migraine?

Answer: You can take another dose at least 1 hour after your first dose if your symptoms persist. **Do not** take more than 2 doses within a 24-hour period. **Do not** take more than 3 doses in a 7-day period. Please refer to the prescribing information for more information.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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