
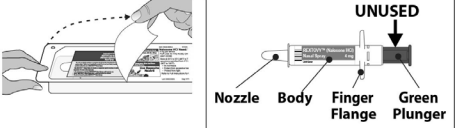
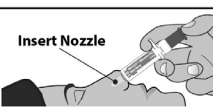












<b>PATIENT INFORMATION</b> <b>REXTOVY (rex toe' vee)</b> <b>(Naloxone Hydrochloride)</b> <b>Nasal Spray</b>																		
<p>You and your family members or caregivers should read this Patient Information leaflet before an opioid emergency happens. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment.</p>																		
<p><b>What is the most important information I should know about REXTOVY™ Nasal Spray?</b>  REXTOVY™ Nasal Spray is used to temporarily reverse the effects of opioid medicines. The medicine in REXTOVY™ Nasal Spray has no effect in people who are not taking opioid medicines. Always carry REXTOVY™ Nasal Spray with you in case of an opioid emergency.</p> <ol style="list-style-type: none"> <li>Use REXTOVY™ Nasal Spray right away if you or your caregiver think signs or symptoms of an opioid emergency are present, even if you are not sure, because an opioid emergency can cause severe injury or death. Signs and symptoms of an opioid emergency may include: <ul style="list-style-type: none"> <li>unusual sleepiness and you are not able to awaken the person with a loud voice or by rubbing firmly on the middle of their chest (sternum)</li> <li>breathing problems including slow or shallow breathing in someone difficult to awaken or who looks like they are not breathing</li> <li>the black circle in the center of the colored part of the eye (pupil) is very small, sometimes called "pinpoint pupils," in someone difficult to awaken</li> </ul> </li> <li>Family members, caregivers, or other people who may have to use REXTOVY™ Nasal Spray in an opioid emergency should know where REXTOVY™ Nasal Spray is stored and how to give REXTOVY™ Nasal Spray before an opioid emergency happens.</li> <li><b>Get emergency medical help right away after giving the first dose of REXTOVY™ Nasal Spray.</b> Rescue breathing or CPR (cardiopulmonary resuscitation) may be given while waiting for emergency medical help.</li> <li>The signs and symptoms of an opioid emergency can return after REXTOVY™ Nasal Spray is given. If this happens, give another dose after 2 minutes, then every 2 to 3 minutes using a new REXTOVY™ Nasal Spray and watch the person closely until emergency help is received.</li> </ol>																		
<p><b>What is REXTOVY™ Nasal Spray?</b></p> <ul style="list-style-type: none"> <li>REXTOVY™ Nasal Spray is a prescription medicine used in adults and children for the treatment of an opioid emergency such as an overdose or a possible opioid overdose with signs of breathing problems and severe sleepiness or not being able to respond.</li> <li>REXTOVY™ Nasal Spray is to be given right away and does not take the place of emergency medical care. Get emergency medical help right away after giving the first dose of REXTOVY™ Nasal Spray, even if the person wakes up.</li> <li>REXTOVY™ Nasal Spray is safe and effective in children for known or suspected opioid overdose.</li> </ul>																		
<p><b>Who should not use REXTOVY™ Nasal Spray?</b>  <b>Do not use REXTOVY™ Nasal Spray</b> if you are allergic to naloxone hydrochloride or any of the ingredients in REXTOVY™ Nasal Spray. See the end of this leaflet for a complete list of ingredients in REXTOVY™ Nasal Spray.</p>																		
<p><b>What should I tell my healthcare provider before using REXTOVY™ Nasal Spray?</b>  Before using REXTOVY™ Nasal Spray, tell your healthcare provider about all of your medical conditions, including if you:</p> <ul style="list-style-type: none"> <li>have heart problems</li> <li>are pregnant or plan to become pregnant. Use of REXTOVY™ Nasal Spray may cause withdrawal symptoms in your unborn baby. Your unborn baby should be examined by a healthcare provider right away after you use REXTOVY™ Nasal Spray.</li> <li>are breastfeeding or plan to breastfeed. It is not known if REXTOVY™ Nasal Spray passes into your breast milk.</li> </ul> <p><b>Tell your healthcare provider about the medicines you take,</b> including prescription and over-the-counter medicines, vitamins, and herbal supplements.</p>																		
<p><b>How should I use REXTOVY™ Nasal Spray?</b>  <b>Read the "Instructions for Use" at the end of this Patient Information leaflet for detailed information about the right way to use REXTOVY™ Nasal Spray.</b></p> <ul style="list-style-type: none"> <li>Use REXTOVY™ Nasal Spray exactly as prescribed by your healthcare provider.</li> <li>Each REXTOVY™ Nasal Spray contains only 1 dose of medicine and cannot be reused.</li> <li>Lay the person on their back. Support their neck with your hand and allow the head to tilt back before giving REXTOVY™ Nasal Spray.</li> <li>REXTOVY™ Nasal Spray should be given into one nostril.</li> <li>Call for emergency medical assistance immediately after the first dose of REXTOVY™ Nasal Spray.</li> <li>If the person responds by waking up to the voice or touch or starts breathing normally, place the person on their side (recovery position).</li> <li>If the person does not respond or stops breathing normally and additional doses are needed, give REXTOVY™ Nasal Spray in the other nostril.</li> </ul>																		
<p><b>What are the possible side effects of REXTOVY™ Nasal Spray?</b>  <b>REXTOVY™ Nasal Spray may cause serious side effects, including:</b></p> <ul style="list-style-type: none"> <li><b>Sudden opioid withdrawal symptoms.</b> In someone who has been using opioids regularly, opioid withdrawal symptoms can happen suddenly after receiving REXTOVY™ Nasal Spray and may include: <table border="0" style="width: 100%;"> <tr> <td>o body aches</td> <td>o sneezing</td> <td>o nervousness</td> </tr> <tr> <td>o diarrhea</td> <td>o goose bumps</td> <td>o restlessness or irritability</td> </tr> <tr> <td>o increased heart rate</td> <td>o sweating</td> <td>o shivering or trembling</td> </tr> <tr> <td>o fever</td> <td>o yawning</td> <td>o stomach cramping</td> </tr> <tr> <td>o runny nose</td> <td>o nausea or vomiting</td> <td>o weakness</td> </tr> <tr> <td>o increased blood pressure</td> <td></td> <td></td> </tr> </table> </li> </ul> <p>In infants under 4 weeks old who have been receiving opioids regularly, sudden opioid withdrawal may be life-threatening if not treated the right way. Signs and symptoms include: seizures, crying more than usual, and increased reflexes.</p>	o body aches	o sneezing	o nervousness	o diarrhea	o goose bumps	o restlessness or irritability	o increased heart rate	o sweating	o shivering or trembling	o fever	o yawning	o stomach cramping	o runny nose	o nausea or vomiting	o weakness	o increased blood pressure		
o body aches	o sneezing	o nervousness																
o diarrhea	o goose bumps	o restlessness or irritability																
o increased heart rate	o sweating	o shivering or trembling																
o fever	o yawning	o stomach cramping																
o runny nose	o nausea or vomiting	o weakness																
o increased blood pressure																		
<p><b>The most common side effects of REXTOVY™ Nasal Spray include</b> tingling in your mouth, and headache.  These are not all of the possible side effects of REXTOVY™ Nasal Spray. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.</p>																		
<p><b>How should I store REXTOVY™ Nasal Spray?</b></p> <ul style="list-style-type: none"> <li>Store at room temperature between 68°F to 77°F (20°C to 25°C). REXTOVY™ Nasal Spray may be stored for short periods between 39°F to 104°F (4°C to 40°C).</li> <li>Do not freeze. Do not expose to temperatures below 39°F (4°C) or above 104°F (40°C).</li> <li>Keep REXTOVY™ Nasal Spray in its box until ready to use. Protect from light.</li> <li>Replace REXTOVY™ Nasal Spray before the expiration date on the box.</li> </ul> <p><b>Keep REXTOVY™ Nasal Spray and all medicines out of the reach of children.</b></p>																		
<p><b>General information about the safe and effective use of REXTOVY™ Nasal Spray.</b>  Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use REXTOVY™ Nasal Spray for a condition for which it was not prescribed. You can ask your pharmacist or healthcare provider for information about REXTOVY™ Nasal Spray that is written for health professionals.</p>																		
<p><b>What are the ingredients in REXTOVY™ Nasal Spray?</b>  <b>Active ingredient:</b> naloxone hydrochloride  <b>Inactive ingredients:</b> sodium chloride, sodium hydroxide to adjust pH and water for injection USP  REXTOVY™ Nasal Spray is not made with natural rubber latex.</p> <p>Distributed by International Medication Systems, Limited, So. El Monte, CA 91733, U.S.A.  For more information, go to <a href="http://www.amphastar.com">www.amphastar.com</a> or call 1-800-423-4136.</p>																		

This Patient Information has been approved by the U.S. Food and Drug Administration.

Issued: 06/2023

<b>Instructions for Use</b> <b>REXTOVY (rex toe' vee)</b> <b>(Naloxone Hydrochloride)</b> <b>Nasal Spray</b>	
<p>You and your family members or caregivers should read the Instructions for Use that comes with REXTOVY™ Nasal Spray before using it. Talk to your healthcare provider if you and your family members or caregivers have any questions about the use of REXTOVY™ Nasal Spray.</p> <p><b>Use REXTOVY™ Nasal Spray for known or suspected opioid overdose in adults and children.</b></p> <p><b>Important: For use in the nose only.</b></p> <ul style="list-style-type: none"> <li>Do not remove or test the REXTOVY™ Nasal Spray until ready to use.</li> <li>Each REXTOVY™ Nasal Spray has 1 dose and cannot be reused.</li> <li>You do not need to prime REXTOVY™ Nasal Spray.</li> </ul> <p><b>How to use REXTOVY™ Nasal Spray:</b></p>	
<b>1</b>	<ul style="list-style-type: none"> <li>Lay person flat on their back.</li> </ul> 
<b>2</b>	<ul style="list-style-type: none"> <li>Peel the blister pack open from top left corner with the arrow.</li> <li>Remove the REXTOVY™ Nasal Spray.</li> </ul> <p><small>Note: REXTOVY™ Nasal Spray freezes at temperatures below 5°F (-15°C). If this happens, the device will not spray. Get emergency medical help right away if this happens. Do not wait for REXTOVY™ Nasal Spray to thaw. REXTOVY™ Nasal Spray may still be used if it has been thawed after being previously frozen.</small></p> 
<b>3</b>	<ul style="list-style-type: none"> <li>Support their neck with your hand and allow the head to tilt back.</li> <li>Gently insert the nozzle <b>all the way</b> into one nostril.</li> </ul> 
<b>4</b>	<ul style="list-style-type: none"> <li>Push the green plunger <b>all the way down until it stops</b> to give the dose.</li> <li>Remove the REXTOVY™ Nasal Spray from nostril after dosing.</li> </ul>  
<b>5</b>	<ul style="list-style-type: none"> <li>Get emergency help right away or call 911.</li> </ul> 
<b>6</b>	<ul style="list-style-type: none"> <li>Watch the person for response.</li> <li>Wait 2 minutes</li> </ul> 
<b>7</b>	<p><b>If No Response, Give 2nd Dose with REXTOVY™ Nasal Spray</b></p> <ul style="list-style-type: none"> <li>If no response, give a 2nd dose with a new REXTOVY™ Nasal Spray in the opposite nostril following the instructions in steps 2 to 4 above.</li> <li>If additional REXTOVY™ Nasal Sprays are available, Steps 2 to 4 may be repeated every 2 to 3 minutes, alternating nostrils, until the person responds or emergency help is received.</li> <li>If the person responds by waking up to the voice or touch or starts breathing normally, place the person on their side (recovery position).</li> <li>Watch the person until emergency help arrives.</li> </ul>   
<b>8</b>	<ul style="list-style-type: none"> <li>Throw away (dispose of) the used REXTOVY™ Nasal Spray in a place that is away from children.</li> </ul> 
<p><b>How should I store REXTOVY™ Nasal Spray?</b></p> <ul style="list-style-type: none"> <li>Store at room temperature between 68°F to 77°F (20°C to 25°C). REXTOVY™ Nasal Spray may be stored for short periods between 39°F to 104°F (4°C to 40°C).</li> <li>Do not freeze. Do not expose to temperatures below 39°F (4°C) or above 104°F (40°C).</li> <li>Keep REXTOVY™ Nasal Spray in its box until ready to use. Protect from light.</li> <li>Replace REXTOVY™ Nasal Spray before the expiration date on the box.</li> </ul> <p><b>Keep REXTOVY™ Nasal Spray and all medicines out of the reach of children.</b></p> <p><small>Distributed by International Medication Systems, Limited, So. El Monte, CA 91733, U.S.A.  For more information, go to <a href="http://www.amphastar.com">www.amphastar.com</a> or call 1-800-423-4136.</small></p> <p><small>This Instructions for Use has been approved by the U.S. Food and Drug Administration. Issued: 06/2023</small></p>	

# Instructions for Use REXTOVY (rex toe' vee) (Naloxone Hydrochloride) Nasal Spray

You and your family members or caregivers should read the Instructions for Use that comes with REXTOVY™ Nasal Spray before using it. Talk to your healthcare provider if you and your family members or caregivers have any questions about the use of REXTOVY™ Nasal Spray.

**Use REXTOVY™ Nasal Spray for known or suspected opioid overdose in adults and children.**

**Important: For use in the nose only.**

- Do not remove or test the REXTOVY™ Nasal Spray until ready to use.
- Each REXTOVY™ Nasal Spray has 1 dose and cannot be reused.
- You do not need to prime REXTOVY™ Nasal Spray.

**How to use REXTOVY™ Nasal Spray:**

1

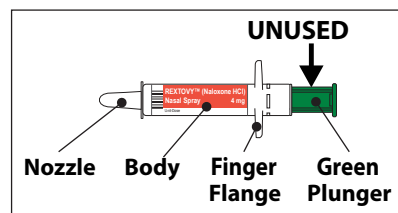
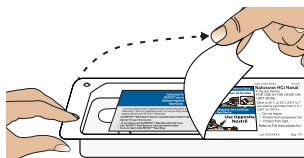
- Lay person flat on their back.



2

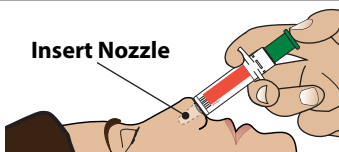
- Peel the blister pack open from top left corner with the arrow.
- Remove the REXTOVY™ Nasal Spray.

**Note:** REXTOVY™ Nasal Spray freezes at temperatures below 5°F (-15°C). If this happens, the device will not spray. Get emergency medical help right away if this happens. Do not wait for REXTOVY™ Nasal Spray to thaw. REXTOVY™ Nasal Spray may still be used if it has been thawed after being previously frozen.



3

- Support their neck with your hand and allow the head to tilt back.
- Gently insert the nozzle **all the way** into one nostril.

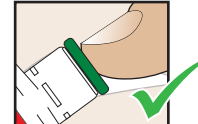


4

- Push the green plunger **all the way down until it stops** to give the dose.
- Remove the REXTOVY™ Nasal Spray from nostril after dosing.



**Push Down All the Way**



5

- Get emergency help right away or call 911.



6

- Watch the person for response.
- Wait 2 minutes

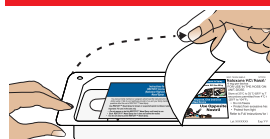


**Wait and Watch!**

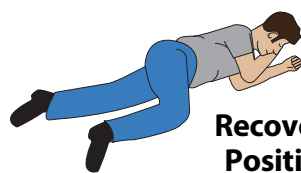


7

- If no response, give a 2nd dose with a new REXTOVY™ Nasal Spray in the opposite nostril following the instructions in steps 2 to 4 above.
- If additional REXTOVY™ Nasal Sprays are available, Steps 2 to 4 may be repeated every 2 to 3 minutes, alternating nostrils, until the person responds or emergency help is received.
- If the person responds by waking up to the voice or touch or starts breathing normally, place the person on their side (recovery position).
- Watch the person until emergency help arrives.



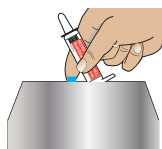
**Use Opposite Nostril**



**Recovery Position**

8

- Throw away (dispose of) the used REXTOVY™ Nasal Spray in a place that is away from children.



## How should I store REXTOVY™ Nasal Spray?

- Store at room temperature between 68°F to 77°F (20°C to 25°C). REXTOVY™ Nasal Spray may be stored for short periods between 39°F to 104°F (4°C to 40°C).
- Do not freeze. Do not expose to temperatures below 39°F (4°C) or above 104°F (40°C).
- Keep REXTOVY™ Nasal Spray in its box until ready to use. Protect from light.
- Replace REXTOVY™ Nasal Spray before the expiration date on the box.

**Keep REXTOVY™ Nasal Spray and all medicines out of the reach of children.**

Distributed by International Medication Systems, Limited, So. El Monte, CA 91733, U.S.A.  
For more information, go to [www.amphastar.com](http://www.amphastar.com) or call 1-800-423-4136.

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

Issued: 06/2023

7036690F/6-23

CC#: 7036690F/6-23  
Date: 6-21-23  
Product: REXTOVY™ (Naloxone HCl) Nasal Spray  
Size: FULL = 8"x 15" FOLDED = 4" x 1"  
Colors: PMS 348C (Rod), PMS 7625C (Syringe Label)  
Reference ID: 5200000

Section 1.14.1.1-5  
Page 1 of 1