

INSTRUCTIONS FOR USE
XOFLUZA® (zoh-FLEW-zuh)
(baloxavir marboxil)
for oral suspension

This **Instruction for Use** contains information on how to prepare and take or give XOFLUZA for oral suspension in packets.

Read these Instructions for Use before preparing and taking or giving XOFLUZA for oral suspension. These Instructions for Use do not take the place of talking to your or your child's healthcare provider about your or your child's medical condition or treatment.

Important information you need to know before preparing and taking or giving XOFLUZA for oral suspension

- XOFLUZA is prescribed as a single, one-time dose.
- Wash your hands before and after preparing, taking, or giving XOFLUZA for oral suspension.
- XOFLUZA for oral suspension packets must be mixed with 1 tablespoon (about 15 to 20 mL) of room temperature drinking water.
- Take or give XOFLUZA for oral suspension right away after mixing.
- Check the expiration date and the product for damage before use. **Do not** use if expired or damaged.
- If you are prescribed the 80 mg dose of XOFLUZA for oral suspension, you will need to take two packets of 40 mg XOFLUZA, one at a time, until your full prescribed dose is taken.
- XOFLUZA for oral suspension can be taken by mouth or given through a feeding tube. Follow your healthcare provider's instructions for giving XOFLUZA through a feeding tube.

Your healthcare provider will prescribe XOFLUZA packets based on your or your child's weight. See the dosing chart below for the prescribed dose and number of XOFLUZA packets needed based on your or your child's weight.

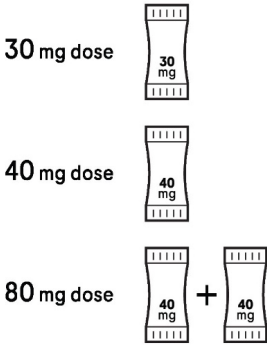
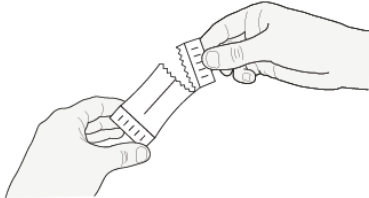
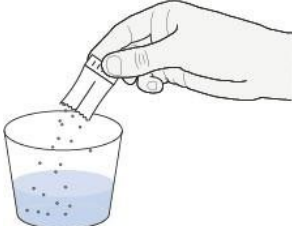
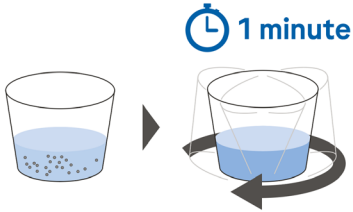

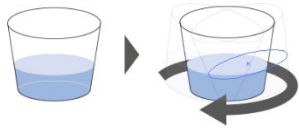
Body weight	Prescribed dose and number of XOFLUZA packets needed
33 lbs (15 kg) to less than 44 lbs (20 kg)	30 mg (One 30 mg packet)
44 lbs (20 kg) to less than 176 lbs (80 kg)	40 mg (One 40 mg packet)
At least 176 lbs (80 kg) and above	80 mg (two 40 mg packets)

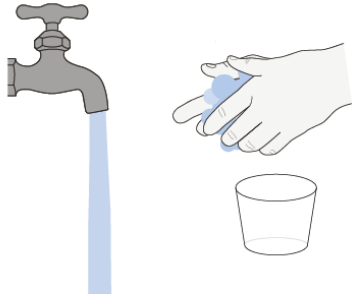
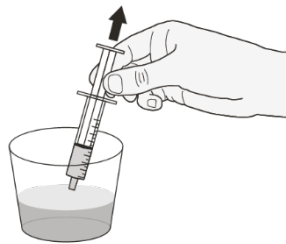

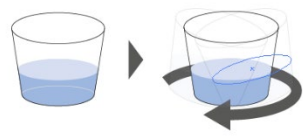
Supplies needed to prepare and take or give XOFLUZA for oral suspension:

- your prescribed dose of XOFLUZA packets
- a tablespoon (about 15 to 20 mL) of room temperature drinking water in a container
- an enteral syringe (if giving XOFLUZA for oral suspension through a feeding tube).

Preparing XOFLUZA for oral suspension

Step 1. Wash and dry your hands.

<p>Step 2: Check your dose</p> <p>Your healthcare provider will prescribe:</p> <ul style="list-style-type: none"> • One 30 mg packet, or • One 40 mg packet, or • Two 40 mg packets for a dose of 80 mg. <p>For the 80 mg dose, you will use two 40 mg packets. Take the packets separately. Follow steps 3 to 7 to take the first packet, then repeat steps 3 to 7 to take the second packet.</p>	
<p>Step 3. Tap the packet to make sure the granules are on one side of the packet.</p> <p>Open the packet by hand or with scissors. (Figure A) Do not cut the granules with the scissor.</p>	 <p>Figure A</p>
<p>Step 4. Add the granules to a small container containing 1 tablespoon (about 15 to 20 mL) of room temperature drinking water. (Figure B)</p> <p>Tap the packet to make sure all granules have been removed.</p>	 <p>Figure B</p>
<p>Step 5. Gently swirl the cup for 1 minute, or until the granules have fully dispersed. (Figure C)</p> <p>Go to Step 6 for taking XOFLUZA for oral suspension by mouth, or</p> <p>Go to Step 10 for giving XOFLUZA for oral suspension through a feeding tube.</p>	 <p>Figure C</p>
<p>Taking XOFLUZA for oral suspension by mouth</p>	
<p>Step 6. Drink the mixture right away. (Figure D)</p>	 <p>Figure D</p>
<p>Step 7. Refill the container with 1 tablespoon (about 15 to 20 mL) of drinking water and swirl to get any remaining granules. (Figure E)</p> <p>Drink right away.</p>	 <p>Figure E</p>

<p>Repeat this step one more time if there are still granules left in the container.</p> <p>If your prescribed dose requires two XOFLUZA packets, repeat Steps 2 through 7.</p>	
<p>Step 8. Wash your hands and all supplies used to take XOFLUZA for oral suspension. (Figure F)</p>	 <p>Figure F</p>
<p>Step 9. Throw away the empty packet and clean the container with soap and water.</p>	
<p>Giving XOFLUZA for oral suspension through a feeding tube</p>	
<ul style="list-style-type: none"> • To take or give XOFLUZA for oral suspension through a feeding tube, review the manufacturer's instructions and consult your healthcare provider. • Give XOFLUZA for oral suspension through a tube that is 4 French or larger. • Follow Steps 2 through 5 to prepare XOFLUZA for oral suspension. • Flush the feeding tube with 1 mL of water before and after feeding tube administration. 	
<p>Step 10</p> <p>Place the enteral syringe tip right away into the container and slowly pull up the plunger to draw up all the oral suspension. (Figure G)</p> <p>Do not wait to draw up the oral suspension. If the mixture sits for too long, it may settle to the bottom, and you may not get the full dose.</p>	 <p>Figure G</p>
<p>Step 11</p> <p>Place the enteral syringe tip into the feeding tube. Slowly push the plunger all the way down to give XOFLUZA. (Figure H)</p>	 <p>Figure H</p>
<p>Step 12</p> <p>Refill the container with 1 tablespoon (about 15 to 20 mL) of drinking water and swirl to get any remaining granules left in the container. (Figure I) Use this water to flush the feeding tube.</p> <p>Repeat this step one more time if there are still granules left in the container.</p>	 <p>Figure I</p>

<p>If your prescribed dose requires 2 XOFLUZA packets, repeat Steps 2 through 5 to prepare the XOFLUZA for oral suspension, then repeat Steps 10 through 12.</p>	
<p>Step 13 Wash your hands with soap and water. Follow the manufacturer's instructions to clean your enteral syringe.</p>	

Storing XOFLUZA for oral suspension in packets
<ul style="list-style-type: none"> • Store XOFLUZA for oral suspension at 68°F to 77°F (20°C to 25°C). • Keep XOFLUZA for oral suspension in the original package. • XOFLUZA for oral suspension in packets has no preservative. • Keep XOFLUZA and all medicines out of reach of children.

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 1 DNA Way, South San Francisco, CA 94080-4990
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