

What are the ingredients in Lazanda?

Active ingredient: fentanyl citrate

Inactive ingredients: mannitol, pectin, phenylethyl alcohol, propylparaben, sucrose, water

Instructions for Use

Before you take Lazanda it is important that you read, understand, and follow the full Medication Guide, including these Instructions for Use. Ask your healthcare provider or pharmacist if you have any questions about the right way to prepare, use, or dispose of Lazanda. Wash your hands with soap and water before and after you use Lazanda.

What will I find in the Lazanda pack?

Each Lazanda pack contains a cardboard box that includes **(See Figure A)**:

- a Medication Guide (not shown)
- a disposal pouch (See Figure B)
- a child-resistant container, which holds 1 bottle of Lazanda.

Take the pouch and the Lazanda bottle in its child-resistant container out of the cardboard box when you are ready to use it. Keep the cardboard box and child-resistant container for storing your Lazanda.

You will need to keep the pouch to safely dispose of any medicine left in the bottle. Do not remove the plastic strip from the pouch until you are ready to seal it.

- Store the Lazanda bottle in the child-resistant container whenever it is not in use.

See the section “How should I store Lazanda?” for more information about storing Lazanda.

Preparing Lazanda for use

Before you use a new bottle of Lazanda for the first time, you will need to prime (prepare) the bottle.

Priming the bottle:

1. Remove the cap from the child-resistant container. To do this, squeeze the raised tabs on the cap and twist the cap to remove **(See Figure C)**. Take the bottle of Lazanda out of the child-resistant container.
2. Remove the protective cap from the nozzle (tip). **(See Figure D)**.
3. Place the tip of the Lazanda bottle into the opening of the pouch. Hold the Lazanda bottle upright so that the spray goes into the pouch (See Figure E).



Figure A



Figure B



Figure C



Figure D

Figure E

4. Look at the counting window. A new unused bottle of Lazanda will show 2 thin red lines in the counting window in the white plastic top on the bottle (See Figure F).



Figure F



Figure G



Figure H



Figure I



Figure J

- Firmly press on the grips and then release. You will hear a “click” and you will see 1 wide red bar in the counting window (**See Figure G**).
- Keep pressing and releasing the grips **3 more times** (for a total of 4 times). Each time, the red bar will become smaller until you see a green bar in the counting window (**See Figures H, I, J**).

5. When you see the green bar, this means that Lazanda is ready for use (**See Figure K**).

6. Remove the tip of the bottle from the pouch. Do not seal the pouch. Do not throw the pouch away.

7. If you are not going to take your medicine right away

- Replace the protective cap
- Put the bottle in its child-resistant container. Put the child-resistant container and pouch in the cardboard box.
- Store the box securely out of the reach of children and pets

8. Wash your hands with soap and water.



Figure K

Re-priming the bottle:

If you have not used the Lazanda bottle for more than 5 days, re-prime by spraying 1 time into the pouch.

Using Lazanda

1. Check to be sure that the Lazanda bottle is ready for use. If the bottle is ready for use, you will see either a green bar (**See Figure L**) or a number (**See Figure M**) in the counting window.



Figure L



Figure M

2. If you have a runny nose, blow your nose now.
3. Remove the protective cap from the nozzle (tip).
4. Sit up with your head upright and hold the Lazanda bottle with your thumb on the bottom of the bottle and your first and middle fingers on the finger grips (**See Figure N**).



Figure N



Figure O



Figure P

Insert the tip a short distance (about ½ inch) into your nose, and point the tip toward the bridge of your nose. This will tilt the bottle slightly (**See Figure O**).

5. Close off the other nostril with 1 finger **(See Figure P)**.
6. Firmly press down on the finger grips until you hear a “click”.
7. Breathe in gently through your nose and out through your mouth 1 time after spraying. Do not sniff after spraying the medicine into your nose.
 - You may not feel the spray go into your nose. This is normal.
 - After you hear the click, you will see that the number in the counting window has increased by 1. This tells you that a spray has been given.
8. If your healthcare provider has prescribed a second spray, repeat steps 4 through 7, but use the other nostril.
9. If your healthcare provider has prescribed four sprays, repeat steps 4 through 7, but use alternate nostrils (for example, right, left, right, left).
10. After each spray, the number in the counting window will increase by 1. When you see a red number “8” in the counting window, the bottle is finished and you will no longer be able to get a full dose from it. You may still see medicine in the bottle, but there is not enough for a full dose. Do not try to take another dose of Lazanda from this bottle.
11. Remain sitting down for at least 1 minute after using Lazanda.
12. Avoid blowing your nose for at least 30 minutes after each spray.
13. Replace the protective cap on the tip of the bottle **(See Figure Q)**. Return the bottle to the child-resistant container after each use, and store securely out of the reach of children.



FigureQ

Disposing of Lazanda

Dispose of the Lazanda bottle when no longer needed:

- If you have used 8 sprays from a bottle, or
- If it has been 60 days or longer since you first used your bottle

Before you throw away the Lazanda bottle, you must empty all the remaining medicine into the pouch. This is to protect others, especially children, from harm.

Disposal of any unused Lazanda

If you can see a number, other than 8 in the counting window, you have NOT used all 8 sprays in the bottle. There are still doses of Lazanda in the bottle.

- You must empty the remaining doses of Lazanda from the bottle
- Put tip in pouch and press and release the grips (**See Figure R**) until the red number “8” appears in the counting window (**See Figure S**)

When you see the number “8” in the counting window (See Figure S), there is still medicine in the bottle that you must spray in the pouch.

- Put the tip into the pouch. (**See Figure R**)
- Press and release the grips a total of 4 times (**See Figure R**)
 - You will feel some increased resistance when you press down
 - You will **not** hear a click when you press down
 - The counter will stay on the red number “8” (**See Figure S**)



Figure R



Figure S

Disposal of Bottle and Pouch

1. Put the protective cap back on the spray bottle. Put the empty bottle back into the child-resistant container.
2. Seal the pouch by removing the plastic strip from the flap and folding the flap over (**See Figures T and U**). Put the sealed pouch into the child-resistant container with the empty bottle.



Figure T



Figure U

3. Place the cap back onto the child-resistant container and twist to close.
4. Throw the child-resistant container with the empty bottle and sealed pouch inside it into the trash.
5. Wash your hands with soap and water.

If you need help with disposal of unused Lazanda bottles, call West Therapeutic Development, LLC at 1-866-458-6389 or call your local Drug Enforcement Administration (DEA) office.

If you lose the pouch, use a pouch from another Lazanda pack to prime and dispose of unused medicine from this bottle as well as from the next bottle. If you do not have an empty pouch available, you can order one by calling 1-866-458-6389. You will receive the replacement pouch in the mail.

If you need to continue using Lazanda, open a new bottle and see the Instructions for Use section of this Medication Guide about “Preparing Lazanda for Use.”

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

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