

Instructions for Use

Prefilled Autoinjector

Important information

NUCALA is a prescription medicine that is injected under the skin (subcutaneous) from a single-dose prefilled autoinjector. You and your caregiver should be trained on how to prepare and perform your injection before trying to do it yourself.

The following instructions provide the information you need to correctly use the prefilled autoinjector with yellow needle guard.

Before starting your injection, it is important that you read and understand these instructions and then carefully follow them so that you complete each step successfully.

Storage information

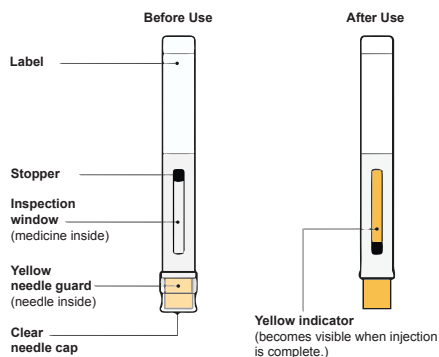
- Store in the refrigerator between 36°F and 46°F (2°C to 8°C).
- Keep in the original carton until time of use to protect from light.
- **Do not** freeze. **Do not** shake. Keep away from heat.
- If necessary, an unopened carton can be stored outside the refrigerator at up to 86°F (30°C) for up to 7 days.
- Safely throw away the prefilled autoinjector if it is left out of the refrigerator in the unopened carton for more than 7 days.
- The prefilled autoinjector must be used within 8 hours after you take it out of the carton. Safely throw it away if it is not used within 8 hours.
- Safely throw away medicine that is out of date or no longer needed.

Keep NUCALA and all medicines out of the reach of children.

Warnings

- **Do not** use the prefilled autoinjector more than 1 time. Throw away the autoinjector in an FDA-cleared sharps disposal container after your injection.
- **Do not** share the prefilled autoinjector with other people. You may give other people a serious infection, or you may get a serious infection from them.
- **Do not** use the prefilled autoinjector if it was dropped or looks damaged.

Know your prefilled autoinjector



Supplies in carton

1 Prefilled autoinjector

Supplies not in carton

- Alcohol swab
 - Cotton ball or gauze
 - Adhesive bandage
 - Sharps disposal container
- (See Step 8 "Throw away your used autoinjector" at the end of this Instructions for Use for proper disposal instructions.)

Please see full Prescribing Information, including Patient Information, for NUCALA available at NUCALA.com.

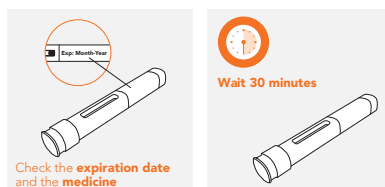
Prepare

1. Take out the prefilled autoinjector



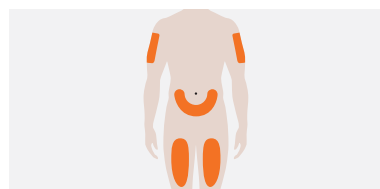
- Take the carton out of the refrigerator and make sure the security seals are not broken.
- Remove the tray from the carton.
- Peel off the clear plastic cover from the corner of the tray.
- Holding the middle of the prefilled autoinjector (near the inspection window), carefully take the prefilled autoinjector out of the tray.
- Place the prefilled autoinjector on a clean, flat surface, at room temperature away from direct sunlight and out of the reach of children
- **Do not** use the prefilled autoinjector if the security seal on the carton is broken. Contact GSK for more information at 1-888-825-5249.
- **Do not** remove the clear needle cap at this step.

2. Inspect and wait 30 minutes before use



- Check that the expiration date on the label of the prefilled autoinjector has not passed.
- Look at the medicine in the inspection window. It should be clear to pale yellow to pale brown in color and without cloudiness or particles.
- It is normal to see 1 or more air bubbles.
- Wait 30 minutes (and no more than 8 hours) before use.
- **Do not** use if the expiration date has passed.
- **Do not** warm your prefilled autoinjector in a microwave, hot water, or direct sunlight.
- **Do not** use if the medicine is cloudy or discolored, or has particles. Contact GSK for more information at 1-888-825-5249.
- **Do not** use the prefilled autoinjector if it has been left out of the carton for more than 8 hours.

3. Choose your injection site



- You can inject in your thighs or abdomen.
- If you are giving the injection to someone else as a caregiver or healthcare provider, you can also inject into their upper arm.
- If you need more than 1 injection to complete your dose, leave at least 2 inches between each injection site.

Do not inject where your skin is bruised, tender, red, or hard.

Do not inject within 2 inches of your belly button.

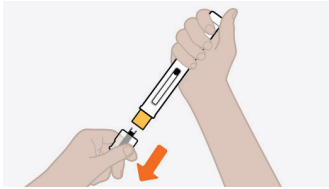
4. Clean your injection site



- Wash your hands with soap and water.
- Clean your injection site by wiping your skin with an alcohol swab and allowing your skin to air dry.
- **Do not** touch your cleaned injection site again until you have finished your injection.

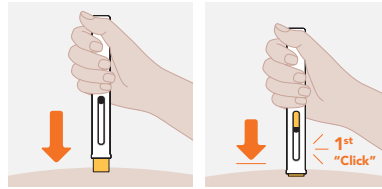
Please see full Prescribing Information, including Patient Information, for NUCALA available at NUCALA.com.

5. Remove the clear needle cap



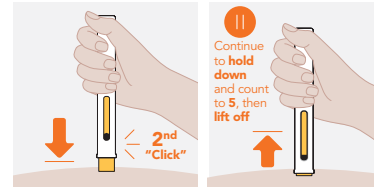
- Remove the clear needle cap from the prefilled autoinjector by pulling it straight off, away from the yellow needle guard (as shown). It may take some force to remove the clear needle cap.
- You may see a drop of medicine at the end of the needle. This is normal.
- Make sure you inject within 5 minutes after you remove the clear needle cap.
- **Do not** press the yellow needle guard with your fingers. This could activate the prefilled autoinjector too soon and cause a needle injury.
- **Do not** put the clear needle cap back onto the prefilled autoinjector. This could accidentally start the injection.

6. Start your injection



- Hold the prefilled autoinjector with its inspection window facing you.
- Place the prefilled autoinjector straight onto your injection site with the yellow needle guard flat on the surface of your skin, as shown.
- To start your injection, push the autoinjector all the way down and keep the autoinjector held down against your skin. This will make the yellow needle guard slide up into the autoinjector.
- You should hear the 1st click to let you know your injection has started.
- The yellow indicator will move down through the inspection window as you receive your dose.
- **Do not** lift the autoinjector at this step as it may result in an incomplete injection.
- **Do not** use the autoinjector if the yellow needle guard does not slide up into the autoinjector. Throw it away in an FDA-cleared sharps container.
- **Do not** try to use the autoinjector upside down with the yellow needle guard facing upward against your thumb.

7. Complete your injection

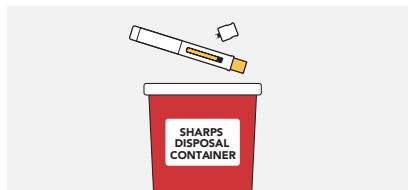


- Your injection may take up to 15 seconds to complete.
- Continue to hold the autoinjector down until you hear the 2nd click, the stopper has stopped moving, and the inspection window is filled with the yellow indicator.
- After you hear the 2nd click, continue to hold and count to 5 before you lift the autoinjector away from your skin.
- If you do not hear the 2nd click:
 - check that the inspection window is filled with the yellow indicator, or
 - hold the autoinjector down for 15 seconds to make sure the injection is complete.
- There may be a small drop of blood at the injection site. This is normal. Press a cotton ball or gauze on the area and apply an adhesive bandage if you need it.
- **Do not** lift the autoinjector until you have heard the 2nd click, the window has been filled with the yellow indicator, and you have counted to 5.
- **Do not** rub your injection site.
- **Do not** put the clear needle cap back onto the autoinjector.

Please see full Prescribing Information, including Patient Information, for NUCALA available at NUCALA.com.

Dispose

8. Throw away your used autoinjector



Put your used autoinjector and clear needle cap in an FDA-cleared sharps disposal container right away after use.

If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:

- made of heavy-duty plastic;
- able to close with a tight-fitting, puncture-resistant lid, without sharps being able to come out;
- upright and stable during use;
- leak-resistant; and
- properly labeled to warn of hazardous waste inside the container.

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of it. There may be state or local laws about how you should throw away used autoinjectors.

For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>.

- o **Do not** throw away your used sharps disposal container in your household trash unless your community guidelines permit this.
- o **Do not** recycle your used sharps disposal container.

Keep your sharps disposal container out of the reach of children.

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Frequently asked questions

1. What happens if the medicine looks cloudy, the expiration date has passed, or the prefilled autoinjector looks damaged?

Contact GSK for more information at 1-888-825-5249.

2. Can I change (rotate) the injection site for the prefilled autoinjector?

You may change (rotate) the site (thigh, abdomen, or upper arm) or move the autoinjector as long as you have not started pressing down. When the yellow needle guard is pressed, your injection will start right away.

3. Why do I need to inject within 5 minutes of removing the clear needle cap?

This prevents the medicine from drying in the needle. It could affect how much medicine you get.

4. What happens if I remove the autoinjector before the 2nd click, the stopper has stopped moving, or the inspection window is not filled with the yellow indicator?

If this happens, you may not have received your full dose. Contact GSK for more information at 1-888-825-5249.

5. Who do I contact if I need help with my injection?

Your healthcare provider will be able to help you with any more questions you might have.

For more information about NUCALA, call 1-888-825-5249 or visit our website at www.NUCALA.com.
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This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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