

Instructions for Use

NUCALA

(mepolizumab)

injection, for subcutaneous use

Prefilled Syringe

Important information

NUCALA is a prescription medicine that is injected under the skin (subcutaneous) from a single-dose prefilled syringe. 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 syringe with automatic 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

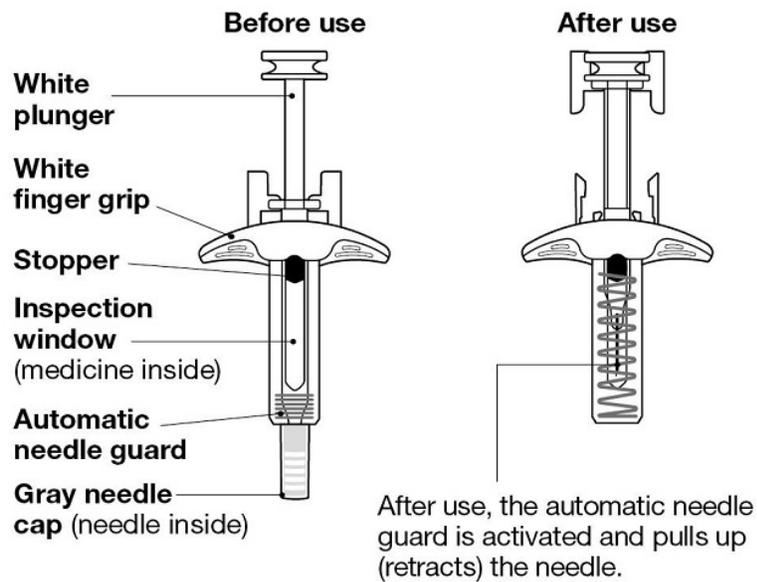
- Store in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Keep in the original carton until time of use to protect from light.
- **Do not** freeze. **Do not** shake. Keep away from heat.
- If necessary, an unopened carton can be stored outside the refrigerator at up to 86°F (30°C) for up to 7 days.
- Safely throw away the prefilled syringe if it is left out of the refrigerator in the unopened carton for more than 7 days.
- The prefilled syringe 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- Safely throw away medicine that is out of date or no longer needed.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 syringe more than 1 time. Throw away the syringe in an FDA-cleared sharps disposal container after your injection.
- **Do not** share the prefilled syringe 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 syringe if it was dropped or looks damaged.

Know your prefilled syringe



Supplies in carton

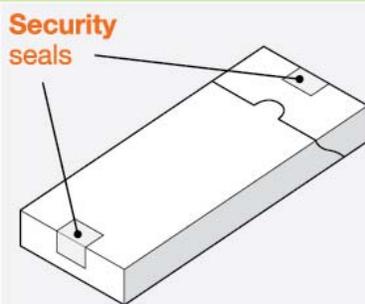
1 Prefilled syringe

Supplies not in carton

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

Prepare

1. Take out the prefilled syringe



Make sure the security seals are not broken

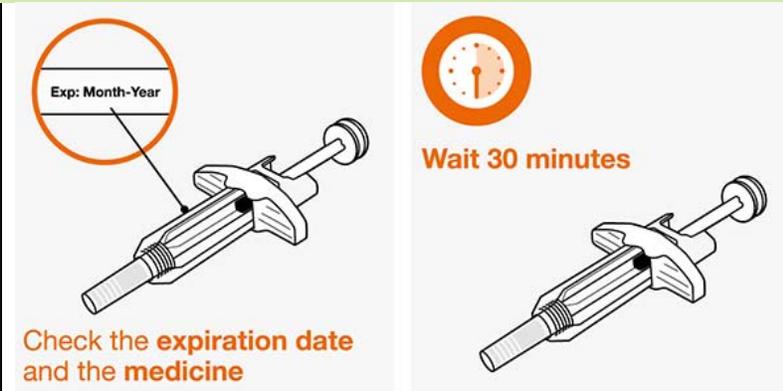


Take the syringe out of the tray

- 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.

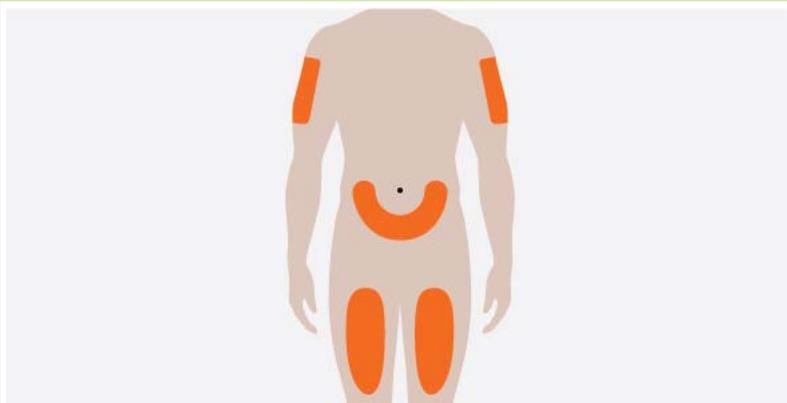
- Holding the middle of the prefilled syringe (near the inspection window), carefully take the prefilled syringe out of the tray.
- Place the prefilled syringe on a clean, flat surface at room temperature away from direct sunlight and out of the reach of children.
 - **Do not** use the prefilled syringe if the security seal on the carton is broken. Contact GSK for more information at 1-888-825-5249.
 - **Do not** remove the gray needle cap at this step.

2. Inspect and wait 30 minutes before use



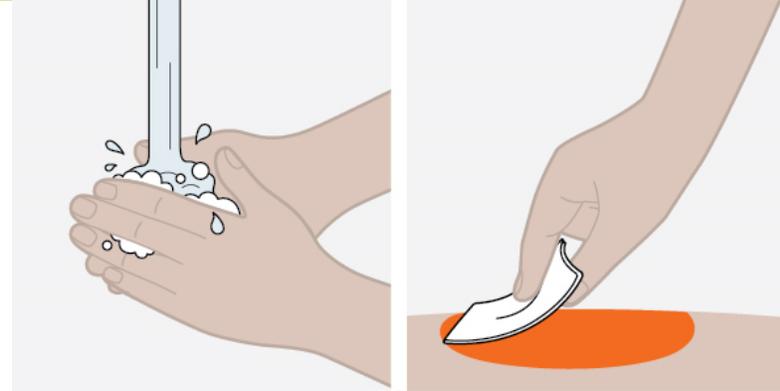
- Check that the expiration date on the label of the prefilled syringe has not passed.
- Look at the medicine in the inspection window. It should be clear to pale yellow to pale brown in color and without cloudiness or particles.
- It is normal to see 1 or more air bubbles.
- Wait 30 minutes (and no more than 8 hours) before use.
 - **Do not** use if the expiration date has passed.
 - **Do not** warm your prefilled syringe 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 syringe 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.

Inject

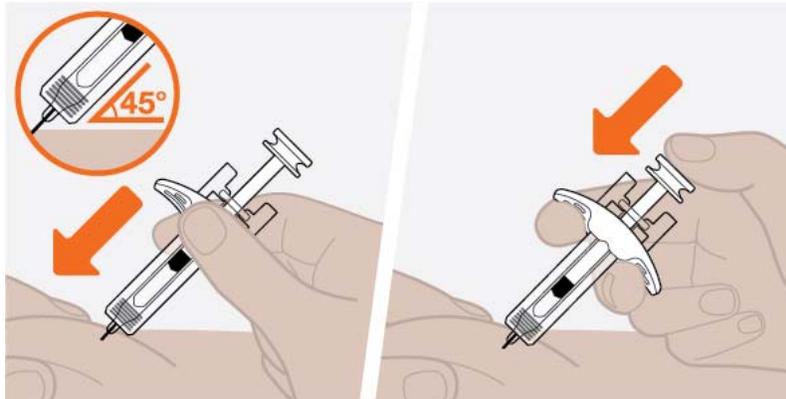
5. Remove the gray needle cap



- Remove the gray needle cap from the prefilled syringe by pulling it straight off, away from the needle (as shown). It may take some force to remove the gray 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 gray needle cap.
 - **Do not** let the needle touch any surface.

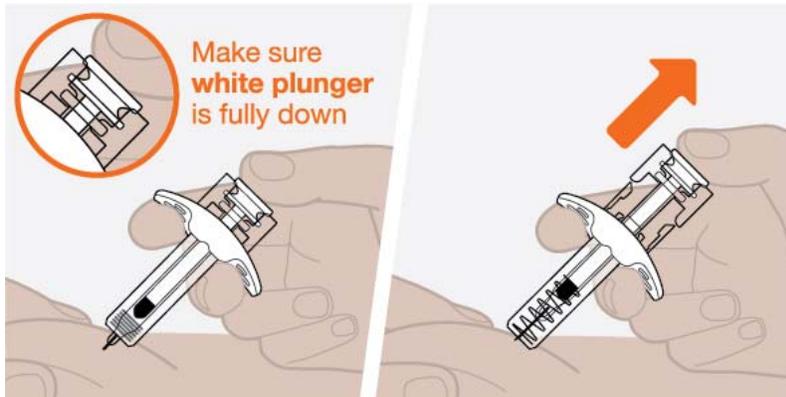
- **Do not** touch the needle.
- **Do not** touch the white plunger at this step. This could accidentally push medicine out, and you will not get your full dose.
- **Do not** try to remove any air bubbles from the prefilled syringe.
- **Do not** put the gray needle cap back onto the prefilled syringe. This could cause a needle injury.

6. Start your injection



- Use your free hand to pinch the skin around your injection site. Keep pinching the skin throughout your injection.
- Insert the entire needle into the pinched skin at a 45° angle, as shown.
- Move your thumb to the white plunger and use your other fingers to hold onto the white finger grip.
- Slowly push down on the white plunger to inject your full dose.

7. Complete your injection



- Make sure the white plunger is pushed all the way down until the stopper reaches the bottom of your syringe and all of the medicine is injected.
- Slowly lift your thumb up. This will allow the white plunger to come up and the needle to automatically retract (pull up) into the body of your syringe.
- After your injection is complete, release the pinched skin.

- 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** rub your injection site.
 - **Do not** put the gray needle cap back onto the syringe.

Dispose

8. Throw away your used syringe



Put your used syringe and gray 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 syringes.

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>.

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

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

Frequently asked questions

1. **What happens if the medicine looks cloudy, the expiration date has passed, or the prefilled syringe looks damaged?**
Contact GSK for more information at 1-888-825-5249.

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

You may change (rotate) the site (thigh, abdomen, or upper arm) as long as you have not started injecting the medicine.

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

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

4. What happens if the needle does not retract (pull up) into the needle guard?

Right away and carefully put the syringe and needle cap in the FDA-cleared sharps disposal container and 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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