



Nucala MPLWCNT210121 Injecting with the Autoinjector User Guide

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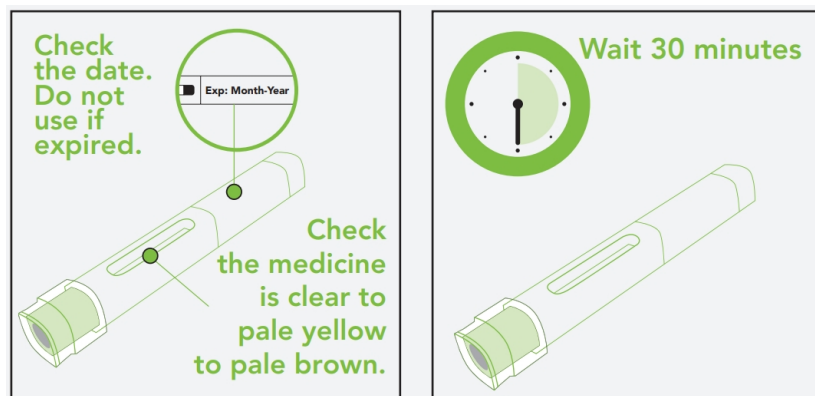
Carefully take Autoinjector out of box. Keep at room temperature, out of direct sunlight. Do not use if left out for more than 8 hours.

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PREP

Inspect and wait 30 minutes before use

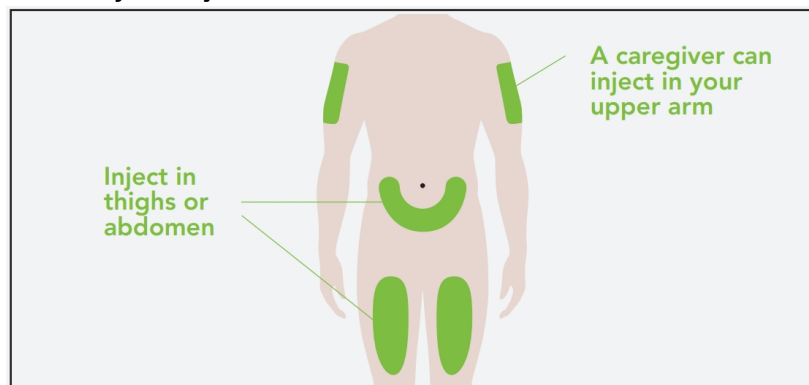


Do not use if the medication is cloudy, discolored, or has particles. A few air bubbles are normal.

Do not remove clear needle cap at this time.

Do not warm in microwave, hot water, or sunlight.

Choose your injection site



NUCALA is injected under the skin.

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

Do not inject within 2 inches of your belly button.

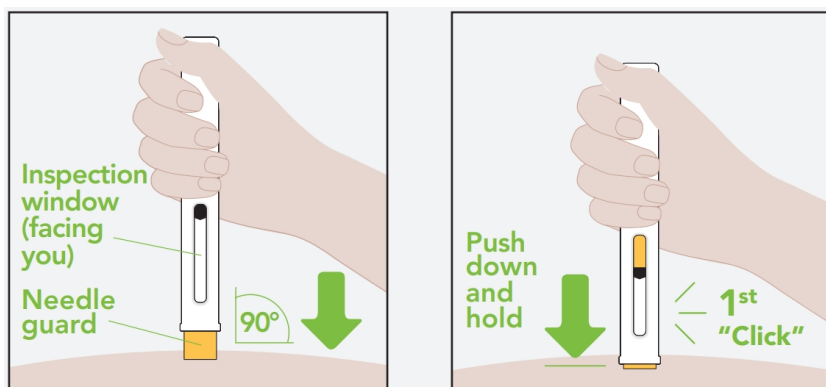
If you need more than 1 injection to complete your dose, leave at least 2 inches between injection sites.

Wash your hands and clean your injection site with an alcohol swab.

INJECT

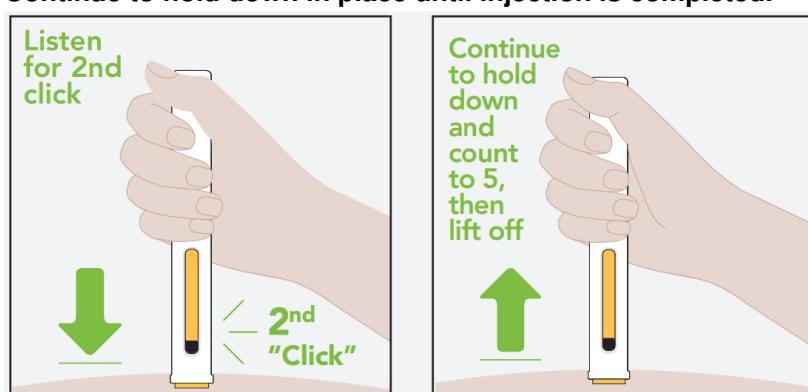
Pull the clear needle cap straight off and **do not** press the yellow needle guard with your fingers. It's normal to see a drop of medicine at the end of the needle. Inject within 5 minutes.

Hold the yellow needle guard FLAT against your skin and push the Autoinjector all the way down and hold.



Listen for the first click, injection has started.
Yellow indicator will move through inspection window.
Do not lift away from skin.

Continue to hold down in place until injection is completed.



2 ways to know you've completed:

1. You have heard the 2nd click and counted to 5.
2. A yellow indicator has filled the inspection window. Injection may take up to 15 seconds.

Please see Important Safety Information on following page.

Please see full Prescribing Information, including Patient Information, for NUCALA available at [NUCALA.com](https://www.nucala.com).

DISPOSE

Do not put the clear needle cap back on. Throw away your used Autoinjector in an approved sharps disposal container right after injecting.



Be sure to talk to your doctor about serious allergic reactions, including anaphylaxis, that can occur after a NUCALA injection, sometimes hours or days later.

Do not use if security seals on Autoinjector carton are broken.

Do not use the Autoinjector more than 1 time.

Do not share the Autoinjector with other people.

Do not use if it was dropped or looks damaged.

Keep NUCALA and all medicines away from children.

Call your doctor if you have any questions.

Watch the How-To-Use Video

Visit [NUCALA.com/howto](https://www.nucala.com/howto) or scan this square with your phone's camera or QR reader to be taken to the video.



Approved Uses for NUCALA Autoinjector

NUCALA is a prescription medicine for the:

- add-on maintenance treatment of patients 12 and older with severe eosinophilic asthma. NUCALA is not used to treat sudden breathing problems.
- add-on maintenance treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adults whose disease is not controlled with nasal corticosteroids.
- treatment of adults with eosinophilic granulomatosis with polyangiitis (EGPA).
- treatment of people 12 years of age and older with hypereosinophilic syndrome (HES).

Important Safety Information

Do not use NUCALA if you are allergic to mepolizumab or any of the ingredients in NUCALA.

Do not use to treat sudden breathing problems.

NUCALA can cause serious side effects, including:

- **allergic (hypersensitivity) reactions, including anaphylaxis.** Serious allergic reactions can happen after you get your NUCALA injection. Allergic reactions can sometimes happen hours or days after you get a dose of NUCALA. Tell your healthcare provider or get emergency help right away if you have any of the following symptoms of an allergic reaction:
 - swelling of your face, mouth, and tongue
 - breathing problems
 - fainting, dizziness, feeling lightheaded (low blood pressure)
 - rash
 - hives
- Herpes zoster infections that can cause shingles have happened in people who received NUCALA.

Before receiving NUCALA, tell your healthcare provider about all of your medical conditions, including if you:

- are taking oral or inhaled corticosteroid medicines. Do not stop taking your other medicines, including your

corticosteroid medicines, unless instructed by your healthcare provider because this may cause other symptoms to come back.

- have a parasitic (helminth) infection.
- are pregnant or plan to become pregnant. It is not known if NUCALA may harm your unborn baby.
 - A pregnancy registry for women with asthma who receive NUCALA while pregnant collects information about the health of you and your baby. You can talk to your healthcare provider about how to take part in this registry or you can get more information and register by calling 1-877-311-8972 or visit www.mothersandchildren.org/asthma.
- are breastfeeding or plan to breastfeed. You and your healthcare provider should decide if you will use NUCALA and breastfeed. You should not do both without talking with your healthcare provider first.
- are taking prescription and over-the-counter medicines, vitamins, and herbal supplements.

The most common side effects of NUCALA include: headache, injection site reactions (pain, redness, swelling, itching, or a burning feeling at the injection site), back pain, and tiredness (fatigue). Mouth/throat pain and joint pain have been reported with CRSwNP.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Instructions for Use

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

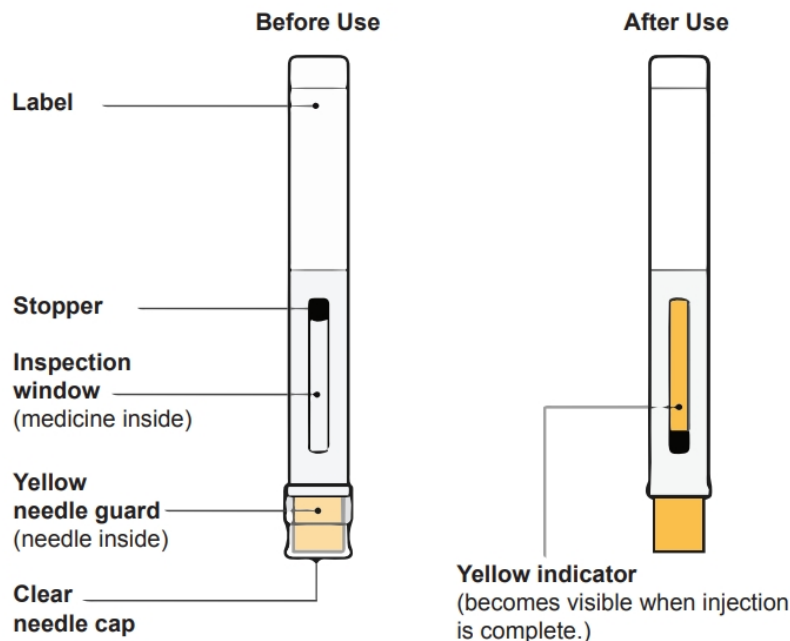
- Store in the refrigerator between 36°F and 46°F (2°C to 8°C).
- Keep in the original carton until time of use to protect from light.
- Do not freeze. Do not shake. Keep away from heat.
- If necessary, an unopened carton can be stored outside the refrigerator at up to 86°F (30°C) for up to 7 days.
- 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

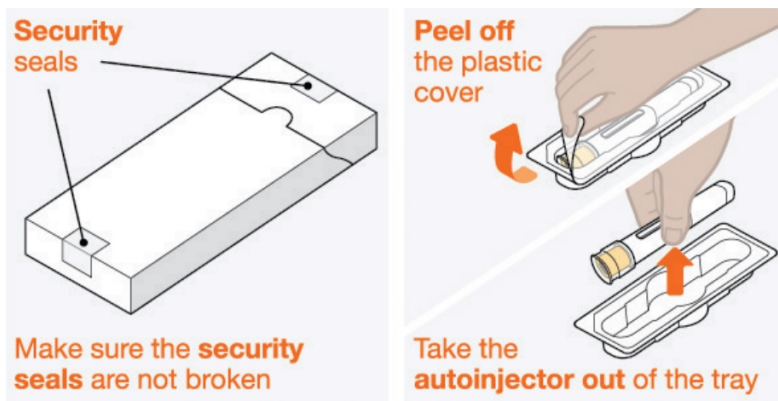
- Alcohol swab
- Cotton ball or gauze
- Adhesive bandage
- Sharps disposal container

(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.

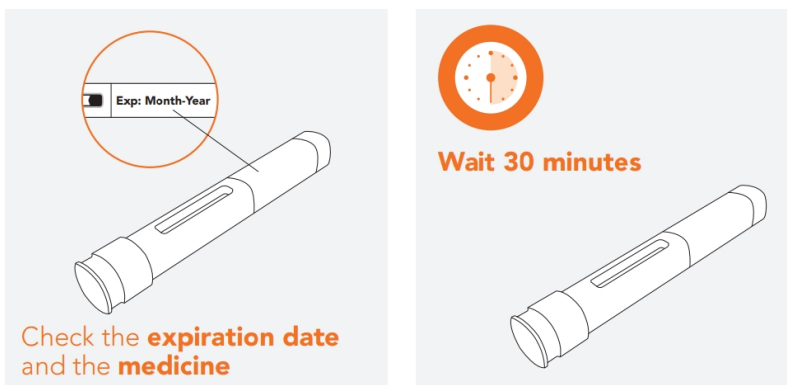
Prepare

Take out the prefilled autoinjector



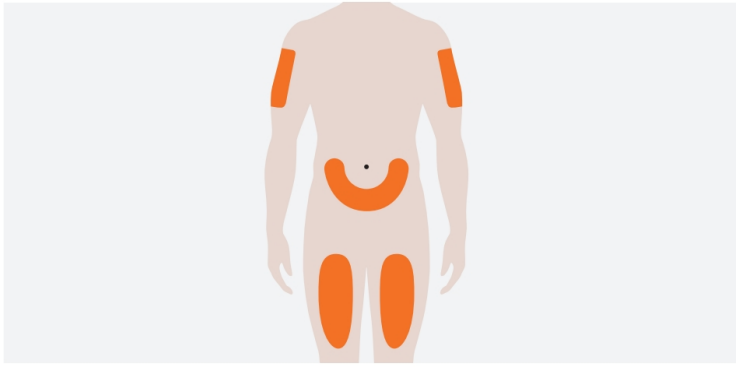
- Take the carton out of the refrigerator and make sure the security seals are not broken.
- Remove the tray from the carton.
- Peel off the clear plastic cover from the corner of the tray.
- Holding the middle of the prefilled autoinjector (near the inspection window), carefully take the prefilled autoinjector 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.

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.

Choose your injection site

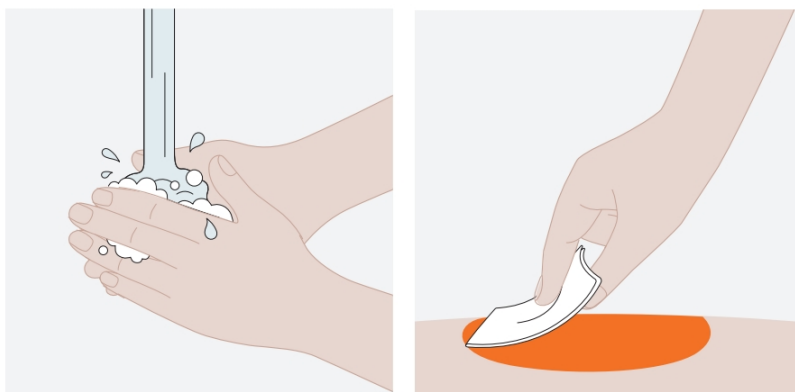


- You can inject in your thighs or abdomen.
- If you are giving the injection to someone else as a caregiver or healthcare provider, you can also inject into their upper arm.
- If you need more than 1 injection to complete your dose, leave at least 2 inches between each injection site.

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

Do not inject within 2 inches of your belly button.

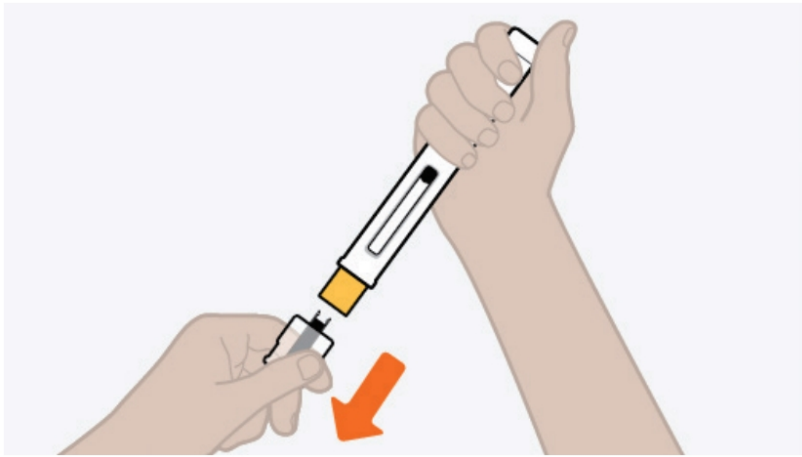
Clean your injection site



- 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.

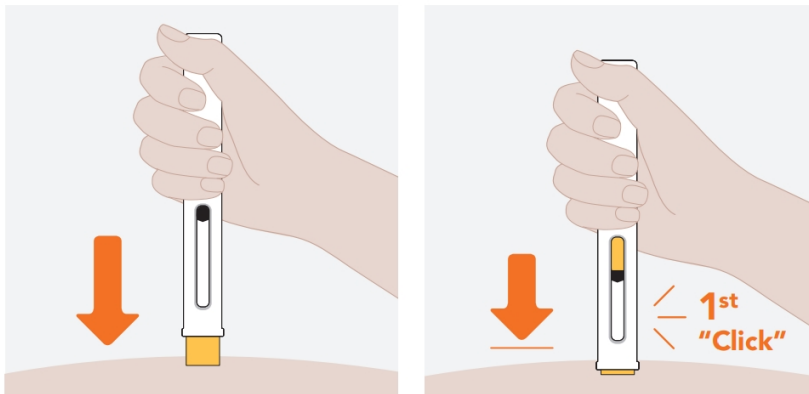
Inject

Remove the clear needle cap



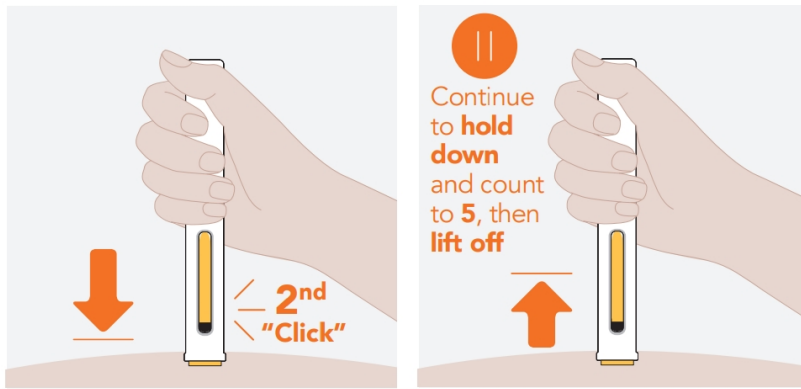
- Remove the clear needle cap from the prefilled autoinjector by pulling it straight off, away from the yellow needle guard (as shown). It may take some force to remove the clear needle cap.
- You may see a drop of medicine at the end of the needle. This is normal.
- Make sure you inject within 5 minutes 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.

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.

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.

Dispose

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>.

- 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 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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NCL:2IFU-A

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

Revised: September 2019

Important Facts About NUCALA

The risk information presented here is not comprehensive and these Important Facts do not take the place of talking to your healthcare provider (HCP). For complete product information, see full Prescribing Information at www.NUCALA.com.

What is NUCALA?

NUCALA is a prescription medicine for the:

- add-on maintenance treatment of severe asthma in people 6 years of age and older whose asthma is not controlled with their current asthma medicines. NUCALA helps prevent severe asthma attacks (exacerbations).

NUCALA is not used to treat sudden breathing problems. It is not known if NUCALA is safe and effective in children with severe asthma under 6 years of age.

- add-on maintenance treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adults whose disease is not controlled with nasal corticosteroid medicines. NUCALA helps reduce symptoms (eg, nasal congestion, nasal discharge, mucus in the throat, loss of smell). NUCALA helps reduce the size of your nasal polyps and the use of oral corticosteroid medicines. NUCALA helps prevent surgery for your nasal polyps. It is not known if NUCALA is safe and effective in children and adolescents with CRSwNP under 18 years of age.
- treatment of adults with eosinophilic granulomatosis with polyangiitis (EGPA). NUCALA helps reduce symptoms and flares, and it may allow your HCP to reduce your oral corticosteroid medicine. It is not known if NUCALA is safe and effective in children and adolescents with EGPA under 18 years of age.
- treatment of people 12 years of age and older with hypereosinophilic syndrome (HES). NUCALA helps reduce symptoms and prevent flares. It is not known if NUCALA is safe and effective in children with HES under 12 years of age.

Medicines such as NUCALA reduce blood eosinophils. Eosinophils are a type of white blood cell that may contribute to your disease.

Do not use NUCALA if you are allergic to mepolizumab or any of the ingredients in NUCALA.

Before receiving NUCALA, tell your HCP about all of your medical conditions, including if you:

- have a parasitic (helminth) infection.
- are taking oral or inhaled corticosteroid medicines. Do not stop taking your corticosteroid medicines unless instructed by your HCP. This may cause other symptoms that were controlled by the corticosteroid medicine to come back.
- are pregnant or plan to become pregnant. It is not known if NUCALA may harm your unborn baby.
 - **Pregnancy Registry.** There is a pregnancy registry for women with asthma
- are breastfeeding or plan to breastfeed. You and your HCP should decide if you will use NUCALA and breastfeed. You should not do both without talking with your HCP first.
- Tell your HCP about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.
- Do not stop taking your other medicines unless instructed to do so by your HCP.

What are the possible side effects of NUCALA?

NUCALA can cause serious side effects, including:

- allergic (hypersensitivity) reactions, including anaphylaxis. Serious allergic reactions can happen after you get your NUCALA injection. Allergic reactions can sometimes happen hours or days after you get a dose of NUCALA. Tell your HCP or get emergency help right away if you have any of the following symptoms of an allergic reaction: swelling of your face, mouth, and tongue; breathing problems; fainting, dizziness, feeling lightheaded (low blood pressure); rash; hives.
- **Herpes zoster infections** that can cause shingles have happened in people who received NUCALA.

The most common side effects of NUCALA include: headache, injection site reactions (pain, redness,

swelling, itching, or a burning feeling at the injection site), back pain, and tiredness (fatigue). Mouth/throat pain and joint pain have been reported with CRSwNP.

These are not all the possible side effects of NUCALA. Call your HCP for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA 1088.

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

The information provided here is not comprehensive. Ask your HCP for additional information about NUCALA. You can also contact the company that makes NUCALA (toll free) at 1-888-825-5249 or at www.NUCALA.com. Trademarks are owned by or licensed to the GSK group of companies who receive NUCALA while pregnant. The purpose of the registry is to collect information about the health of you and your baby. You can talk to your HCP about how to take part in this registry or you can get more information and register by calling 1-877-311-8972 or go to www.mothertobaby.org/asthma.

Support

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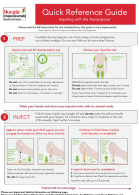
GlaxoSmithKline
Research Triangle Park, NC 27709

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MPLOGM210031 September 2021
Produced in USA. 0002-0014-28

Visit NUCALA.com
Or call 1-844-4-NUCALA (1-844-468-2252)





Documents / Resources

	Nucale MPLWCNT210121 Injecting with the Autoinjector [pdf] User Guide MPLWCNT210121 Injecting with the Autoinjector, MPLWCNT210121, Injecting with the Autoinjector
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References

- [Severe Asthma Treatment | NUCALA \(mepolizumab\)](#)
- [How to Inject NUCALA at Home | NUCALA \(mepolizumab\)](#)
- [MedWatch: The FDA Safety Information and Adverse Event Reporting Program | FDA](#)
- [Safely Using Sharps \(Needles and Syringes\) at Home, at Work and on Travel | FDA](#)

-  [Asthma - MotherToBaby](#)
-  [Severe Asthma Treatment | NUCALA \(mepolizumab\)](#)

Manuals+.