

INJECTING WITH XOLAIR

Following training from your
healthcare provider

**An overview on how to administer
the XOLAIR prefilled syringe or the
XOLAIR autoinjector to yourself or
as a caregiver.**

Use in conjunction with the complete Instructions
for Use enclosed with your XOLAIR

What is XOLAIR?

XOLAIR® (omalizumab) for subcutaneous use is an injectable prescription medicine used to treat:

- moderate to severe persistent asthma in people 6 years of age and older whose asthma symptoms are not well controlled with asthma medicines called inhaled corticosteroids. A skin or blood test is performed to see if you have allergies to year-round allergens. It is not known if XOLAIR is safe and effective in people with asthma under 6 years of age.
- chronic rhinosinusitis with nasal polyps (CRSwNP) in people 18 years of age and older when medicines to treat CRSwNP called nasal corticosteroids have not worked well enough. It is not known if XOLAIR is safe and effective in people with CRSwNP under 18 years of age.
- food allergy in people 1 year of age and older to reduce allergic reactions that may occur after accidentally eating one or more foods to which you are allergic. While taking XOLAIR you should continue to avoid all foods to which you are allergic. It is not known if XOLAIR is safe and effective in people with food allergy under 1 year of age.
- chronic spontaneous urticaria (CSU, previously referred to as chronic idiopathic urticaria (CIU), chronic hives without a known cause) in people 12 years of age and older who continue to have hives that are not controlled with H1 antihistamine treatment. It is not known if XOLAIR is safe and effective in people with CSU under 12 years of age.

XOLAIR should not be used for the emergency treatment of any allergic reactions, including anaphylaxis. XOLAIR should also not be used to treat other forms of hives, or sudden breathing problems.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about XOLAIR?

Severe allergic reaction. A severe allergic reaction called anaphylaxis can happen when you receive XOLAIR. The reaction can occur after the first dose, or after many doses. It may also occur right after a XOLAIR injection or days later. Anaphylaxis is a life-threatening condition and can lead to death.

Please see full Prescribing Information, including Medication Guide, for additional Important Safety Information and Instructions for Use.

Xolair
Omalizumab
FOR SUBCUTANEOUS USE 75 mg • 150 mg • 300 mg

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Please see full [Prescribing Information](#), including [Medication Guide](#), for additional Important Safety Information and [Instructions for Use](#).



XOLAIR dosage strengths and devices

XOLAIR comes in 3 dosage strengths:

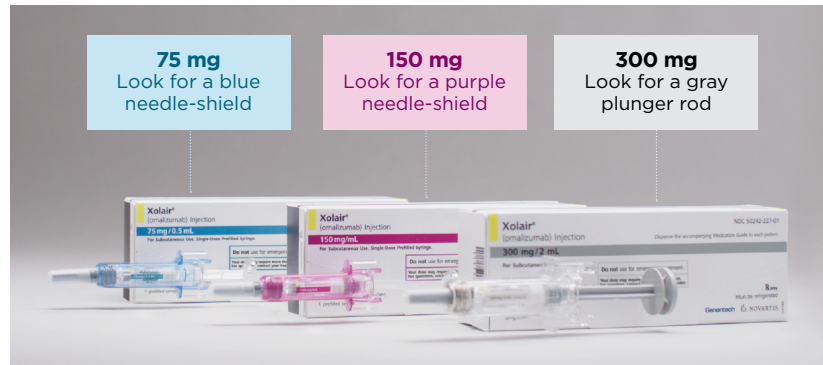
- 75 mg
- 150 mg
- 300 mg

You may need 1 dosage strength or a combination of strengths based on the full dose prescribed by your doctor. Your prescribed dose may require more than 1 injection.

XOLAIR comes in prefilled syringes and autoinjectors. See below for details.

Prefilled syringe

Not actual size.



IMPORTANT SAFETY INFORMATION (continued)

What is the most important information I should know about XOLAIR? (continued)

Severe allergic reaction. (continued)

Go to the nearest emergency room right away if you have any of these symptoms of an allergic reaction:

- wheezing, shortness of breath, cough, chest tightness, or trouble breathing
- low blood pressure, dizziness, fainting, rapid or weak heartbeat, anxiety, or feeling of “impending doom”
- flushing, itching, hives, or feeling warm
- swelling of the throat or tongue, throat tightness, hoarse voice, or trouble swallowing

My dosage:

Autoinjector

Not actual size.



IMPORTANT SAFETY INFORMATION (continued)

What is the most important information I should know about XOLAIR? (continued)

Severe allergic reaction. (continued)

Your healthcare provider will monitor you closely for symptoms of an allergic reaction while you are receiving XOLAIR and for a period of time after treatment is initiated. Your healthcare provider should talk to you about getting medical treatment if you have symptoms of an allergic reaction.

Please see full **Prescribing Information**, including **Medication Guide**, for additional Important Safety Information and **Instructions for Use**.

Things to know about injecting XOLAIR

Your healthcare provider will decide if self-injection with XOLAIR is right for you.

- When starting treatment, XOLAIR should be given by your healthcare provider in a healthcare setting
- If your doctor decides that you or a caregiver may be able to give your own XOLAIR prefilled syringe or autoinjector injections, you should receive training on the right way to prepare and inject XOLAIR
- The XOLAIR autoinjector (all doses) is intended for use only in adults and adolescents 12 years of age and older. For children 12 years and older, the XOLAIR prefilled syringe or autoinjector may be self-injected under adult supervision. For children 1 to 11 years of age, the XOLAIR prefilled syringe should be injected by a caregiver
- DO NOT inject XOLAIR until you or your caregiver have received training from your healthcare provider
- Your healthcare provider will help you recognize the signs and symptoms of a severe allergic reaction and what to do if this occurs
- Use XOLAIR exactly as prescribed by your healthcare provider
- Keep the prefilled syringe or autoinjector out of the reach of children
- Read the full Medication Guide and Instructions for Use within the package insert that comes with XOLAIR for information on how to properly prepare, inject, store, and dispose of prefilled syringes or autoinjectors
- Talk to your healthcare provider if you have any questions

IMPORTANT SAFETY INFORMATION (continued)

Do not receive and use XOLAIR if you are allergic to omalizumab or any of the ingredients in XOLAIR.

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

- have a latex allergy or any other allergies (such as seasonal allergies). The needle cap on the XOLAIR prefilled syringe contains a type of natural rubber latex.
- have sudden breathing problems (bronchospasm)
- have ever had a severe allergic reaction called anaphylaxis
- have or have had a parasitic infection

Preparing the prefilled syringe or autoinjector

Bring to room temperature

XOLAIR should be refrigerated at 36 °F to 46 °F (2 °C to 8 °C) in the original carton, but it needs to be at room temperature before you can inject it. Take the XOLAIR carton out of the refrigerator and leave it unopened while it gradually comes to room temperature. If more than 1 prefilled syringe or autoinjector is needed, take them all out at the same time. The following steps must be followed for each prefilled syringe or autoinjector.

Prefilled syringe, 75 mg and 150 mg: 15-30 minutes

Prefilled syringe, 300 mg: 30-45 minutes

Autoinjector, all doses: 30-45 minutes

Do not speed up the warming process using any heat source such as warm water or a microwave.

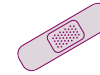
Gather your supplies



Your XOLAIR



Alcohol swab



Bandage



Cotton ball
or gauze



Sharps disposal
container

Lay everything on a flat, clean surface.

Preparing to inject

- After washing your hands thoroughly with soap and water, check the expiration date on the prefilled syringe or autoinjector carton. If the expiration date has passed, safely throw away the prefilled syringe or autoinjector in a sharps disposal container and contact your healthcare provider.
- If the expiration date has passed, open the prefilled syringe blister pack or autoinjector carton. Do not flip the blister pack or carton upside down.
- Hold the prefilled syringe or autoinjector in the center when you pick it up. The medicine inside should be clear and colorless to pale brownish-yellow.

IMPORTANT SAFETY INFORMATION (continued)

Before receiving XOLAIR, tell your healthcare provider about all of your medical conditions, including if you: (continued)

- have or have had cancer
- are pregnant or plan to become pregnant. It is not known if XOLAIR may harm your unborn baby.

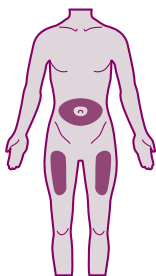
Please see full **Prescribing Information**, including **Medication Guide**, for additional Important Safety Information and **Instructions for Use**.



Self-injecting with the 75 mg and 150 mg prefilled syringe

Preparing to inject

Where to inject



Inject in the front of the thigh or the stomach area. Avoid the belly button by at least 2 inches.

If your prescribed dose requires more than 1 injection, choose a different injection site for each new injection, at least 1 inch from other injection sites. It's also important to rotate sites each time you administer an injection.

- For children 12 years of age and older, the XOLAIR prefilled syringe may be self-administered under adult supervision
- For children 1 to 11 years old, the XOLAIR prefilled syringe should be administered by a caregiver



Do not administer injections:

- Through clothing
- Within 2 inches of the belly button
- Into moles or scar tissue
- Into skin that is bruised, red, hard, or broken

If you need assistance with handling the prefilled syringe while pinching the skin or finding the appropriate angle for your injection, please contact your doctor.

IMPORTANT SAFETY INFORMATION (continued)

Before receiving XOLAIR, tell your healthcare provider about all of your medical conditions, including if you: (continued)

- are breastfeeding or plan to breastfeed. It is not known if XOLAIR passes into your breast milk. Talk with your healthcare provider about the best way to feed your baby while you receive and use XOLAIR.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Giving the injection

How to inject*



Clean the injection site with an alcohol swab in a circular motion and let it air-dry naturally for 10 seconds. **Do not** fan or blow on the cleaned skin. **Do not** touch the injection site again before giving the injection.



Hold the prefilled syringe firmly with one hand and pull the needle cap straight off with the other hand. **Do not** touch the needle or let it touch any surface after removing the needle cap.



With your other hand, gently pinch the area of skin you just cleaned. Hold the pinched skin tightly until the injection is complete.



Insert the needle all the way into the pinched skin using a quick, dart-like motion at a **45- to 90-degree angle**. **Do not** touch the plunger while inserting the needle into the skin.



Gently push the plunger all the way down until the needle-shield wings are pushed apart.



Release the plunger and allow the needle to be covered by the needle-shield.

*Shown here is the 150 mg prefilled syringe.

After the injection

Cleaning up



Do not rub the injection site. If there is a little bleeding, apply a cotton ball, gauze, or bandage.



Dispose of your used prefilled syringe in an FDA-cleared sharps disposal container immediately after use.

If your prescribed dose requires more than 1 injection, complete all the required injections for your prescribed dose, immediately one after another.

Visit [fda.gov/safesharpsdisposal](https://www.fda.gov/safesharpsdisposal) for more information.

IMPORTANT SAFETY INFORMATION (continued)

How should I receive and use XOLAIR?

- When starting treatment, XOLAIR should be given by your healthcare provider in a healthcare setting.
- If your healthcare provider decides that you or a caregiver may be able to give your own XOLAIR prefilled syringe or autoinjector injections, you should receive training on the right way to prepare and inject XOLAIR.

Please see full **Prescribing Information**, including **Medication Guide**, for additional Important Safety Information and **Instructions for Use**.

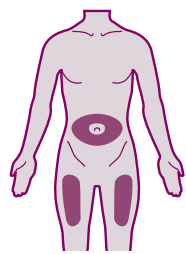
Xolair
Omalizumab
FOR SUBCUTANEOUS USE 75 mg • 150 mg • 300 mg

Assisted injection with the 75 mg and 150 mg prefilled syringe

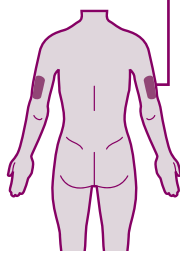
If you are injecting a child, ask them where they would like to receive their injection: in their playroom, bedroom, or wherever they feel most comfortable.

Preparing to inject

Where to inject



front



back

Caregiver
use only

If you're giving the injection to a child or another adult, you can inject in the outer area of the upper arm, the front of the thigh, or the stomach area. Avoid the belly button by at least 2 inches.

If the prescribed dose requires more than 1 injection, choose a different injection site for each new injection, at least 1 inch from other injection sites. It's also important to rotate sites each time you administer an injection.

- For children 12 years of age and older, the XOLAIR prefilled syringe may be self-administered under adult supervision
- For children 1 to 11 years of age, the XOLAIR prefilled syringe should be administered by a caregiver



Do not administer injections:

- Through clothing
- Within 2 inches of the belly button
- Into moles or scar tissue
- Into skin that is bruised, red, hard, or broken

If you need assistance with handling the prefilled syringe while pinching the skin or finding the appropriate angle for the injection, contact your doctor.

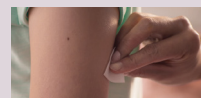
IMPORTANT SAFETY INFORMATION (continued)

How should I receive and use XOLAIR? (continued)

- Do not try to inject XOLAIR until you have been shown the right way to give XOLAIR prefilled syringe or autoinjector injections by a healthcare provider. Use XOLAIR exactly as prescribed by your healthcare provider.

Giving the injection

How to inject*



Clean the injection site with an alcohol swab in a circular motion and let it air-dry naturally for 10 seconds. **Do not** fan or blow on the cleaned skin. **Do not** touch the injection site again before giving the injection.



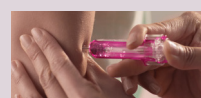
Hold the prefilled syringe firmly with one hand and pull the needle cap straight off with the other hand. **Do not** touch the needle or let it touch any surface after removing the needle cap.



With your other hand, gently pinch the area of skin you just cleaned. Hold the pinched skin tightly until the injection is complete.



Insert the needle all the way into the pinched skin using a quick, dart-like motion at a **45- to 90-degree angle**. **Do not** touch the plunger while inserting the needle into the skin.



Gently push the plunger all the way down until the needle-shield wings are pushed apart.

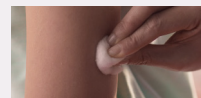


Release the plunger and allow the needle to be covered by the needle-shield.

*Shown here is the 150 mg prefilled syringe.

After the injection

Cleaning up



Do not rub the injection site. If there is a little bleeding, apply a cotton ball, gauze, or bandage.



Dispose of the used prefilled syringe in an FDA-cleared sharps disposal container immediately after use.

If your prescribed dose requires more than 1 injection, complete all the required injections for your prescribed dose, immediately one after another.

Visit [fda.gov/safesharpsdisposal](https://www.fda.gov/safesharpsdisposal) for more information.

IMPORTANT SAFETY INFORMATION (continued)

How should I receive and use XOLAIR? (continued)

- The XOLAIR autoinjector (all doses) is intended for use only in adults and adolescents aged 12 years and older. For children 12 years of age and older, XOLAIR prefilled syringe or autoinjector may be self-injected under adult supervision. For children 1 to 11 years of age, XOLAIR prefilled syringe should be injected by a caregiver.

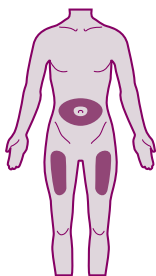
Please see full **Prescribing Information**, including **Medication Guide**, for additional Important Safety Information and **Instructions for Use**.



Self-injecting with the 300 mg prefilled syringe

Preparing to inject

Where to inject



Inject in the front of the thigh or the stomach area. Avoid the belly button by at least 2 inches.

If your prescribed dose requires more than 1 injection, choose a different injection site for each new injection, at least 1 inch from other injection sites. It's also important to rotate sites each time you administer an injection.

- For children 12 years of age and older, the XOLAIR prefilled syringe may be self-administered under adult supervision
- For children 1 to 11 years old, the XOLAIR prefilled syringe should be administered by a caregiver



Do not administer injections:

- Through clothing
- Within 2 inches of the belly button
- Into moles or scar tissue
- Into skin that is bruised, red, hard, or broken

If you need assistance with handling the prefilled syringe while pinching the skin or finding the appropriate angle for your injection, please contact your doctor.

IMPORTANT SAFETY INFORMATION (continued)

How should I receive and use XOLAIR? (continued)

- See the detailed Instructions for Use that comes with XOLAIR for information on the right way to prepare and inject XOLAIR.
- XOLAIR is given in 1 or more injections under the skin (subcutaneous), 1 time every 2 or 4 weeks.
- In people with asthma, CRSwNP, and food allergy, a blood test for a substance called IgE must be performed before starting XOLAIR to determine the appropriate dose and dosing frequency.

Giving the injection

How to inject*



Clean the injection site with an alcohol swab in a circular motion and let it air-dry naturally for 10 seconds. **Do not** fan or blow on the cleaned skin. **Do not** touch the injection site again before giving the injection.



Hold the prefilled syringe firmly with one hand and pull the needle cap straight off with the other hand. **Do not** touch the needle or let it touch any surface after removing the needle cap.



With your other hand, gently pinch the area of skin you just cleaned. Hold the pinched skin tightly until the injection is complete.



Insert the needle all the way into the pinched skin using a quick, dart-like motion at a **45-degree angle**. **Do not** touch the plunger while inserting the needle into the skin.



Gently push the plunger all the way down until the plunger head is between the safety guard wings.



Release the plunger and allow the needle to be covered by the needle-shield.

*Shown here is the 300 mg prefilled syringe.

After the injection

Cleaning up



Do not rub the injection site. If there is a little bleeding, apply a cotton ball, gauze, or bandage.



Dispose of your used prefilled syringe in an FDA-cleared sharps disposal container immediately after use.

If your prescribed dose requires more than 1 injection, complete all the required injections for your prescribed dose, immediately one after another.

Visit [fda.gov/safesharpsdisposal](https://www.fda.gov/safesharpsdisposal) for more information.

IMPORTANT SAFETY INFORMATION (continued)

How should I receive and use XOLAIR? (continued)

- In people with chronic hives, a blood test is not necessary to determine the dose or dosing frequency.

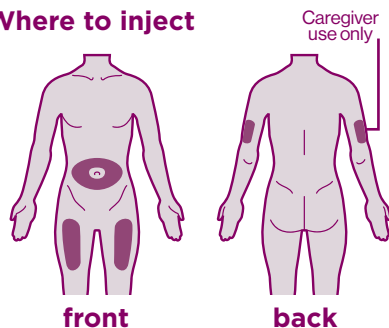
Please see full **Prescribing Information**, including **Medication Guide**, for additional Important Safety Information and **Instructions for Use**.

Assisted injection with the 300 mg prefilled syringe

If you are injecting a child, ask them where they would like to receive their injection: in their playroom, bedroom, or wherever they feel most comfortable.

Preparing to inject

Where to inject



If you're giving the injection to a child or another adult, you can inject in the outer area of the upper arm, the front of the thigh, or the stomach area. Avoid the belly button by at least 2 inches.

If the prescribed dose requires more than 1 injection, choose a different injection site for each new injection, at least 1 inch from other injection sites. It's also important to rotate sites each time you administer an injection.

- For children 12 years of age and older, the XOLAIR prefilled syringe may be self-administered under adult supervision
- For children 1 to 11 years of age, the XOLAIR prefilled syringe should be administered by a caregiver



Do not administer injections:

- Through clothing
- Within 2 inches of the belly button
- Into moles or scar tissue
- Into skin that is bruised, red, hard, or broken

If you need assistance with handling the prefilled syringe while pinching the skin or finding the appropriate angle for the injection, contact your doctor.

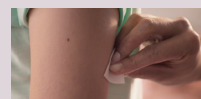
IMPORTANT SAFETY INFORMATION (continued)

How should I receive and use XOLAIR? (continued)

- Do not decrease or stop taking any of your other asthma, CRSwNP, hive medicine, food allergy medicine or allergen immunotherapy, unless your healthcare providers tell you to.
- You may not see improvement in your symptoms right away after XOLAIR treatment. If your symptoms do not improve or get worse, call your healthcare provider.

Giving the injection

How to inject*



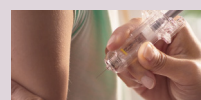
Clean the injection site with an alcohol swab in a circular motion and let it air-dry naturally for 10 seconds. **Do not** fan or blow on the cleaned skin. **Do not** touch the injection site again before giving the injection.



Hold the prefilled syringe firmly with one hand and pull the needle cap straight off with the other hand. **Do not** touch the needle or let it touch any surface after removing the needle cap.



With your other hand, gently pinch the area of skin you just cleaned. Hold the pinched skin tightly until the injection is complete.



Insert the needle all the way into the pinched skin using a quick, dart-like motion at a **45-degree angle**. **Do not** touch the plunger while inserting the needle into the skin.



Gently push the plunger all the way down until the plunger head is between the safety guard wings.

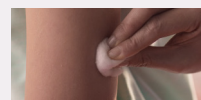


Release the plunger and allow the needle to be covered by the needle-shield.

*Shown here is the 300 mg prefilled syringe.

After the injection

Cleaning up



Do not rub the injection site. If there is a little bleeding, apply a cotton ball, gauze, or bandage.



Dispose of the used prefilled syringe in an FDA-cleared sharps disposal container immediately after use.

If your prescribed dose requires more than 1 injection, complete all the required injections for your prescribed dose, immediately one after another.

Visit [fda.gov/safesharpsdisposal](https://www.fda.gov/safesharpsdisposal) for more information.

IMPORTANT SAFETY INFORMATION (continued)

How should I receive and use XOLAIR? (continued)

- If you inject more XOLAIR than prescribed, call your healthcare provider right away.

What are the possible side effects of XOLAIR?

XOLAIR may cause serious side effects, including:

- **Cancer.** Cases of cancer were observed in some people who received XOLAIR.

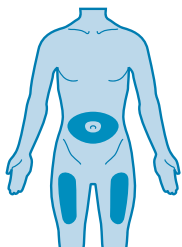
Please see full **Prescribing Information**, including **Medication Guide**, for additional Important Safety Information and **Instructions for Use**.



Self-injecting with the autoinjector

Preparing to inject

Where to inject



Inject in the front of the thigh or the stomach area. Avoid the belly button by at least 2 inches.

If your prescribed dose requires more than 1 injection, choose a different injection site for each new injection, at least 1 inch from other injection sites. It's also important to rotate sites each time you administer an injection.

- For children 12 years of age and older, the XOLAIR autoinjector may be self-administered under adult supervision
- The XOLAIR autoinjector (all doses) is **not** intended for or approved for use in children under 12 years of age

Do not administer injections:



- Through clothing
- Within 2 inches of the belly button
- Into moles or scar tissue
- Into skin that is bruised, red, hard, or broken

If you need assistance with handling the autoinjector or finding the appropriate angle for your injection, contact your doctor.

IMPORTANT SAFETY INFORMATION (continued)

XOLAIR may cause serious side effects, including: (continued)

- **Inflammation of your blood vessels.** Rarely, this can happen in people with asthma who receive XOLAIR. This usually, but not always, happens in people who also take a steroid medicine by mouth that is being stopped or the dose is being lowered. It is not known whether this is caused by XOLAIR. Tell your healthcare provider right away if you have rash; chest pain; shortness of breath; or a feeling of pins and needles or numbness of your arms or legs.

Giving the injection

How to inject



Clean the injection site with an alcohol swab in a circular motion and let it air-dry naturally for 10 seconds. **Do not** fan or blow on the cleaned skin. **Do not** touch the injection site again before giving the injection.



Hold the autoinjector firmly with one hand and pull the needle cap straight off with the other hand.



Hold the autoinjector comfortably with the needle guard directly against the skin at a **90-degree angle**. To start the injection, press straight down and hold the autoinjector firmly against the skin. The 1st click indicates that the injection has started. **Do not** change your position until the injection is completed.



Hold the autoinjector tightly in place. Monitor the injection using the green indicator. Keep holding the autoinjector against the skin. The green indicator will move within the viewing window.



Listen for the 2nd click. This indicates that the injection is **almost** complete. Hold the autoinjector in position until the green indicator with the gray stopper has stopped moving and completely fills the viewing window to make sure the injection is complete.



After the green indicator with the gray stopper has stopped moving and has completely filled the viewing window, lift the autoinjector straight up from the skin. The needle guard will automatically extend and lock over the needle.

After the injection

Cleaning up



Do not rub the injection site. If there is a little bleeding, apply a cotton ball, gauze, or bandage.



Dispose of the used autoinjector in an FDA-cleared sharps disposal container immediately after use.

If your prescribed dose requires more than 1 injection, complete all the required injections for your prescribed dose, immediately one after another.

Visit [fda.gov/safesharpsdisposal](https://www.fda.gov/safesharpsdisposal) for more information.

IMPORTANT SAFETY INFORMATION (continued)

XOLAIR may cause serious side effects, including: (continued)

- **Fever, muscle aches, and rash.** Some people get these symptoms 1 to 5 days after receiving a XOLAIR injection. If you have any of these symptoms, tell your healthcare provider.

Please see full **Prescribing Information**, including **Medication Guide**, for additional Important Safety Information and **Instructions for Use**.

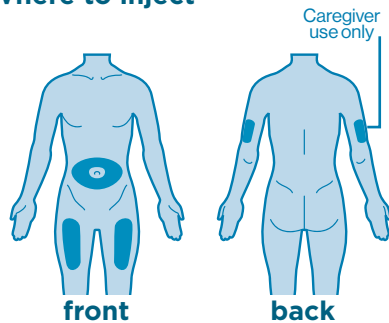


Assisted injection with the autoinjector

If you are injecting a child, ask them where they would like to receive their injection: in their playground, bedroom, or wherever they feel most comfortable.

Preparing to inject

Where to inject



If you're giving the injection to a child or another adult, you can inject the outer area of the upper arm, the front of the thigh, or the stomach area. Avoid the belly button by at least 2 inches. If the prescribed dose requires more than 1 injection, choose a different injection site for each new injection, at least 1 inch from other injection sites. It's also important to rotate sites each time you administer an injection.

- For children 12 years of age and older, the XOLAIR autoinjector may be self-administered under adult supervision
- The XOLAIR autoinjector (all doses) is **not** intended for or approved for use in children under 12 years of age

Do not administer injections:



- Through clothing
- Within 2 inches of the belly button
- Into moles or scar tissue
- Into skin that is bruised, red, hard, or broken

If you need assistance with handling the autoinjector or finding the appropriate angle for the injection, contact your doctor.

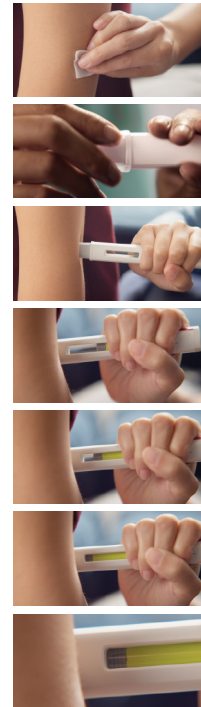
IMPORTANT SAFETY INFORMATION (continued)

XOLAIR may cause serious side effects, including: (continued)

- **Parasitic infection.** Some people who are at a high risk for parasite (worm) infections, get a parasite infection after receiving XOLAIR. Your healthcare provider can test your stool to check if you have a parasite infection.

Giving the injection

How to inject



Clean the injection site with an alcohol swab in a circular motion and let it air-dry naturally for 10 seconds. **Do not** fan or blow on the cleaned skin. **Do not** touch the injection site again before giving the injection.

Hold the autoinjector firmly with one hand and pull the needle cap straight off with the other hand.

Hold the autoinjector comfortably with the needle guard directly against the skin at a **90-degree angle**.

To start the injection, press straight down and hold the autoinjector firmly against the skin. The 1st click indicates that the injection has started. **Do not** change your position until the injection is completed.

Hold the autoinjector tightly in place. Monitor the injection using the green indicator. Keep holding the autoinjector against the skin. The green indicator will move within the viewing window.

Listen for the 2nd click. This indicates that the injection is **almost** complete. Hold the autoinjector in position until the green indicator with the gray stopper has stopped moving and completely fills the viewing window to make sure the injection is complete.

After the green indicator with the gray stopper has stopped moving and has completely filled the viewing window, lift the autoinjector straight up from the skin. The needle guard will automatically extend and lock over the needle.

After the injection

Cleaning up



Do not rub the injection site. If there is a little bleeding, apply a cotton ball, gauze, or bandage.



Dispose of the used autoinjector in an FDA-cleared sharps disposal container immediately after use.

If your prescribed dose requires more than 1 injection, complete all the required injections for your prescribed dose, immediately one after another.

Visit [fda.gov/safesharpsdisposal](https://www.fda.gov/safesharpsdisposal) for more information.

IMPORTANT SAFETY INFORMATION (continued)

XOLAIR may cause serious side effects, including: (continued)

- **Heart and circulation problems.** Some people who receive XOLAIR have had chest pain, heart attack, blood clots in the lungs or legs, or temporary symptoms of weakness on one side of the body, slurred speech, or altered vision. It is not known whether these are caused by XOLAIR.

Please see full **Prescribing Information**, including **Medication Guide**, for additional Important Safety Information and **Instructions for Use**.



Injection FAQ

What should I do if I forget how to self-inject or feel uncertain?

Call your doctor's office and ask for another training session.

You can also:

- Learn about additional virtual training at [XOLAIR.com](https://www.xolair.com)
- Call 866-4-XOLAIR (866-496-5247) if you have any questions
- Watch a step-by-step video of how to inject XOLAIR at [XOLAIR.com](https://www.xolair.com)

What should I do if the XOLAIR carton is damaged?

Do not use if the packaging is damaged or appears to be tampered with, as it may not be safe for you to use. Call your doctor's office for guidance.

What should I do if the prefilled syringe or autoinjector itself is damaged or past its expiration date?

Safely throw away the prefilled syringe or autoinjector in a sharps disposal container and contact your doctor.

What if I leave the prefilled syringe or autoinjector out for too long?

Temperature change may affect the medicine. The prefilled syringe or autoinjector should not be used after 48 hours (2 days) at room temperature. If this happens, **do not** use the prefilled syringe or autoinjector and call your doctor's office.

What happens if I forget to take my XOLAIR?

Call your doctor to discuss when you should inject the next dose.

IMPORTANT SAFETY INFORMATION (continued)

The most common side effects of XOLAIR:

- **In adults and children 12 years of age and older with asthma:** joint pain especially in your arms and legs, dizziness, feeling tired, itching, skin rash, bone fractures, and pain or discomfort of your ears.
- **In children 6 to less than 12 years of age with asthma:** swelling of the inside of your nose, throat, or sinuses, headache, fever, throat infection, ear infection, abdominal pain, stomach infection, and nose bleeds.
- **In adults with chronic rhinosinusitis with nasal polyps:** headache, injection site reactions, joint pain, upper abdominal pain, and dizziness.
- **In people with chronic spontaneous urticaria:** nausea, headaches, swelling of the inside of your nose, throat or sinuses, cough, joint pain, and upper respiratory tract infection.
- **In people with food allergy:** injection site reactions and fever.

These are not all the possible side effects of XOLAIR. Call your doctor for medical advice about side effects.

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at (888) 835-2555 or Novartis Pharmaceuticals Corporation at (888) 669-6682.

IMPORTANT SAFETY INFORMATION (continued)

XOLAIR may cause serious side effects, including: (continued)

- **Heart and circulation problems.** Some people who receive XOLAIR have had chest pain, heart attack, blood clots in the lungs or legs, or temporary symptoms of weakness on one side of the body, slurred speech, or altered vision. It is not known whether these are caused by XOLAIR.

Please see full [Prescribing Information](#), including [Medication Guide](#), for additional Important Safety Information and [Instructions for Use](#).



What is XOLAIR?

XOLAIR® (omalizumab) for subcutaneous use is an injectable prescription medicine used to treat:

- moderate to severe persistent asthma in people 6 years of age and older whose asthma symptoms are not well controlled with asthma medicines called inhaled corticosteroids. A skin or blood test is performed to see if you have allergies to year-round allergens. It is not known if XOLAIR is safe and effective in people with asthma under 6 years of age.
- chronic rhinosinusitis with nasal polyps (CRSwNP) in people 18 years of age and older when medicines to treat CRSwNP called nasal corticosteroids have not worked well enough. It is not known if XOLAIR is safe and effective in people with CRSwNP under 18 years of age.
- food allergy in people 1 year of age and older to reduce allergic reactions that may occur after accidentally eating one or more foods to which you are allergic. While taking XOLAIR you should continue to avoid all foods to which you are allergic. It is not known if XOLAIR is safe and effective in people with food allergy under 1 year of age.
- chronic spontaneous urticaria (CSU, previously referred to as chronic idiopathic urticaria (CIU), chronic hives without a known cause) in people 12 years of age and older who continue to have hives that are not controlled with H1 antihistamine treatment. It is not known if XOLAIR is safe and effective in people with CSU under 12 years of age.

XOLAIR should not be used for the emergency treatment of any allergic reactions, including anaphylaxis. XOLAIR should also not be used to treat other forms of hives, or sudden breathing problems.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about XOLAIR?

Severe allergic reaction. A severe allergic reaction called anaphylaxis can happen when you receive XOLAIR. The reaction can occur after the first dose, or after many doses. It may also occur right after a XOLAIR injection or days later. Anaphylaxis is a life-threatening condition and can lead to death. Go to the nearest emergency room right away if you have any of these symptoms of an allergic reaction:

- wheezing, shortness of breath, cough, chest tightness, or trouble breathing
- low blood pressure, dizziness, fainting, rapid or weak heartbeat, anxiety, or feeling of “impending doom”
- flushing, itching, hives, or feeling warm
- swelling of the throat or tongue, throat tightness, hoarse voice, or trouble swallowing

Your healthcare provider will monitor you closely for symptoms of an allergic reaction while you are receiving XOLAIR and for a period of time after treatment is initiated. Your healthcare provider should talk to you about getting medical treatment if you have symptoms of an allergic reaction.

IMPORTANT SAFETY INFORMATION (continued)

Do not receive and use XOLAIR if you are allergic to omalizumab or any of the ingredients in XOLAIR.

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

- have a latex allergy or any other allergies (such as seasonal allergies). The needle cap on the XOLAIR prefilled syringe contains a type of natural rubber latex.
- have sudden breathing problems (bronchospasm)
- have ever had a severe allergic reaction called anaphylaxis
- have or have had a parasitic infection
- have or have had cancer
- are pregnant or plan to become pregnant. It is not known if XOLAIR may harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if XOLAIR passes into your breast milk. Talk with your healthcare provider about the best way to feed your baby while you receive and use XOLAIR.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I receive and use XOLAIR?

- When starting treatment, XOLAIR should be given by your healthcare provider in a healthcare setting.
- If your healthcare provider decides that you or a caregiver may be able to give your own XOLAIR prefilled syringe or autoinjector injections, you should receive training on the right way to prepare and inject XOLAIR.
- Do not try to inject XOLAIR until you have been shown the right way to give XOLAIR prefilled syringe or autoinjector injections by a healthcare provider. Use XOLAIR exactly as prescribed by your healthcare provider.
- The XOLAIR autoinjector (all doses) is intended for use only in adults and adolescents aged 12 years and older. For children 12 years of age and older, XOLAIR prefilled syringe or autoinjector may be self-injected under adult supervision. For children 1 to 11 years of age, XOLAIR prefilled syringe should be injected by a caregiver.
- See the detailed Instructions for Use that comes with XOLAIR for information on the right way to prepare and inject XOLAIR.
- XOLAIR is given in 1 or more injections under the skin (subcutaneous), 1 time every 2 or 4 weeks.

Please see full Prescribing Information, including Medication Guide, for additional Important Safety Information and Instructions for Use.



IMPORTANT SAFETY INFORMATION (continued)

How should I receive and use XOLAIR? (continued)

- In people with asthma, CRSwNP, and food allergy, a blood test for a substance called IgE must be performed before starting XOLAIR to determine the appropriate dose and dosing frequency.
- In people with chronic hives, a blood test is not necessary to determine the dose or dosing frequency.
- Do not decrease or stop taking any of your other asthma, CRSwNP, hive medicine, food allergy medicine or allergen immunotherapy, unless your healthcare providers tell you to.
- You may not see improvement in your symptoms right away after XOLAIR treatment. If your symptoms do not improve or get worse, call your healthcare provider.
- If you inject more XOLAIR than prescribed, call your healthcare provider right away.

What are the possible side effects of XOLAIR?

XOLAIR may cause serious side effects, including:

- **Cancer.** Cases of cancer were observed in some people who received XOLAIR.
- **Inflammation of your blood vessels.** Rarely, this can happen in people with asthma who receive XOLAIR. This usually, but not always, happens in people who also take a steroid medicine by mouth that is being stopped or the dose is being lowered. It is not known whether this is caused by XOLAIR. Tell your healthcare provider right away if you have rash; chest pain; shortness of breath; or a feeling of pins and needles or numbness of your arms or legs.
- **Fever, muscle aches, and rash.** Some people get these symptoms 1 to 5 days after receiving a XOLAIR injection. If you have any of these symptoms, tell your healthcare provider.
- **Parasitic infection.** Some people who are at a high risk for parasite (worm) infections, get a parasite infection after receiving XOLAIR. Your healthcare provider can test your stool to check if you have a parasite infection.
- **Heart and circulation problems.** Some people who receive XOLAIR have had chest pain, heart attack, blood clots in the lungs or legs, or temporary symptoms of weakness on one side of the body, slurred speech, or altered vision. It is not known whether these are caused by XOLAIR.

IMPORTANT SAFETY INFORMATION (continued)

The most common side effects of XOLAIR:

- **In adults and children 12 years of age and older with asthma:** joint pain especially in your arms and legs, dizziness, feeling tired, itching, skin rash, bone fractures, and pain or discomfort of your ears.
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These are not all the possible side effects of XOLAIR. Call your doctor for medical advice about side effects.

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Please see full **Prescribing Information**, including **Medication Guide**, for additional Important Safety Information and **Instructions for Use**.



Visit XOLAIR.com for additional resources on self-injection such as injection training videos and the Instructions for Use.



You can also schedule a one-on-one education session with a Clinical Education Manager* trained to provide information on XOLAIR and support programs available. Call **1-866-878-0493** for more information.

And, as always, call **1-866-4-XOLAIR** (1-866-496-5247) for any general questions you may have.

*Clinical Education Managers are Genentech employees and do not give medical advice. Please consult your doctor for medical advice.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about XOLAIR?

Severe allergic reaction. A severe allergic reaction called anaphylaxis can happen when you receive XOLAIR. The reaction can occur after the first dose, or after many doses. It may also occur right after a XOLAIR injection or days later. Anaphylaxis is a life-threatening condition and can lead to death. Go to the nearest emergency room right away if you have any of these symptoms of an allergic reaction:

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Genentech
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 **NOVARTIS**

Xolair
Omalizumab
FOR SUBCUTANEOUS USE 75 mg + 150 mg + 300 mg