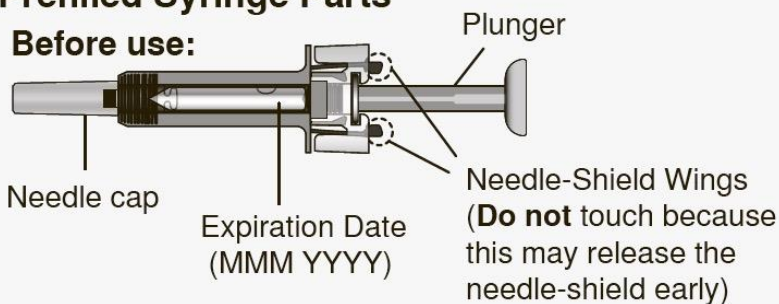


**Instructions for Use**  
**Xolair® (ZOHL-air)**  
(omalizumab)  
**Prefilled Syringe**

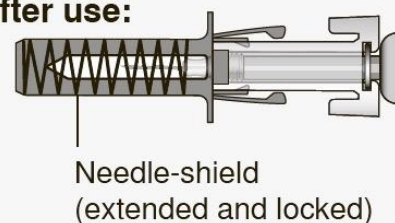
Read this Instructions for Use before you start using the XOLAIR prefilled syringe and each time you get a refill. Before you use the XOLAIR prefilled syringe for the first time, make sure your healthcare provider shows you the right way to use it. Contact your healthcare provider if you have any questions.

**Prefilled Syringe Parts**

**Before use:**



**After use:**

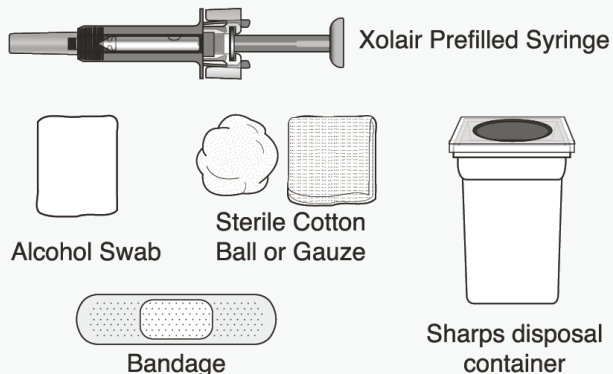


**Supplies needed to give your injection**

- XOLAIR prefilled syringes (You may need more than 1 prefilled syringe for your prescribed dose). See **“Choose the correct prefilled syringe or combination of prefilled syringes”** for more information. Each XOLAIR carton contains 1 prefilled syringe.

The following supplies are not included in the carton:

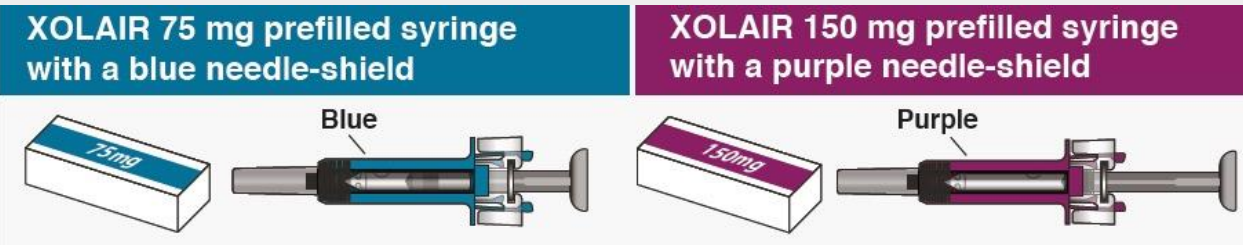
- Alcohol swab
- Sterile cotton ball or gauze
- Small bandage
- Sharps disposal container (see **step 14 “After the Injection”**)














### Choose the correct prefilled syringe or combination of prefilled syringes

XOLAIR prefilled syringes are available in 2 dose strengths. These instructions are to be used for both dose strengths.

Your prescribed dose may require more than 1 injection. The table below shows the combination of prefilled syringes needed to give your full dose. Check the label on the XOLAIR carton to make sure you have received the correct prefilled syringe or combination of prefilled syringes for your prescribed dose. If your dose requires more than 1 injection, inject the medicine from all of your prescribed prefilled syringes, immediately one after another. Contact your healthcare provider if you have any questions.



Dose	Syringes needed for the dose	75 mg	150 mg
75 mg	1 blue (75 mg)		
150 mg	1 purple (150 mg)		
225 mg	1 blue (75 mg) + 1 purple (150 mg)		
300 mg	2 purple (150 mg)		
375 mg	1 blue (75 mg) + 2 purple (150 mg)		
450 mg	3 purple (150 mg)		
525 mg	1 blue (75 mg) + 3 purple (150 mg)		
600 mg	4 purple (150 mg)		

### How should I store XOLAIR?

- Keep your unused prefilled syringes in the original carton and store the carton in a refrigerator between 36°F to 46°F (2°C to 8°C). **Do not** remove the prefilled syringe from its original carton during storage.
- Keep your XOLAIR prefilled syringes out of direct sunlight.
- **Do not** freeze. Do not use if the prefilled syringe has been frozen.

**Keep the XOLAIR prefilled syringe, sharps disposal container and all medicines out of the reach of children.**

### Important Information

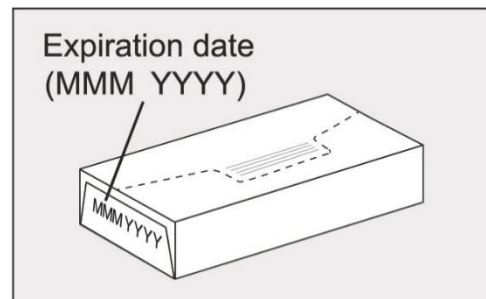
- The needle cap contains a type of natural rubber latex. Tell your healthcare provider if you have a latex allergy.
- Inject XOLAIR within 4 hours after taking it out of the refrigerator.
- **Do not** open the sealed carton until you are ready to inject XOLAIR.
- **Do not** take the needle cap off until you are ready to inject XOLAIR.
- **Do not** try to take the prefilled syringe apart at any time.
- **Do not** reuse the same prefilled syringe.
- **Do not** leave the prefilled syringe unattended.

### Preparing for the Injection

#### 1 Take the carton containing the prefilled syringe out of the refrigerator.

- If your dose requires you to give more than 1 injection, take all cartons out of the refrigerator at the same time. The following steps must be followed for **each** prefilled syringe.

#### 2 Check the expiration date on the XOLAIR carton.



- **Do not** use if the expiration date has passed.
- If the expiration date has passed, safely throw away the prefilled syringe in a sharps disposal container (see **step 14**) and contact your healthcare provider.

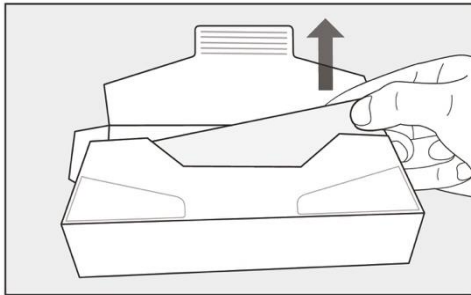
## Preparing for the Injection

### 3 Place the carton on a clean, flat surface.

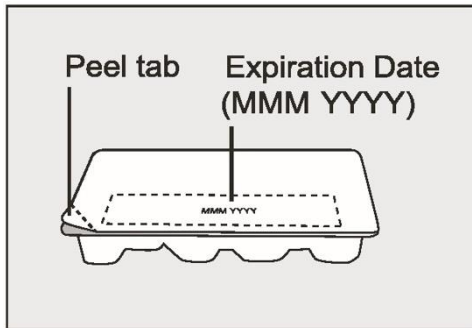
- Set aside the carton for at least 15 to 30 minutes so the prefilled syringe can warm up on its own to room temperature. Leave the prefilled syringe in the carton to protect it from light.
- If the prefilled syringe does not reach room temperature, this could cause the injection to feel uncomfortable and make it hard to push the plunger.
- **Do not** speed up the warming process using any heat sources such as warm water or a microwave.

## Preparing for the Injection

### 4 Open the carton.



- Wash your hands with soap and water.
- Take the blister pack out of the carton.

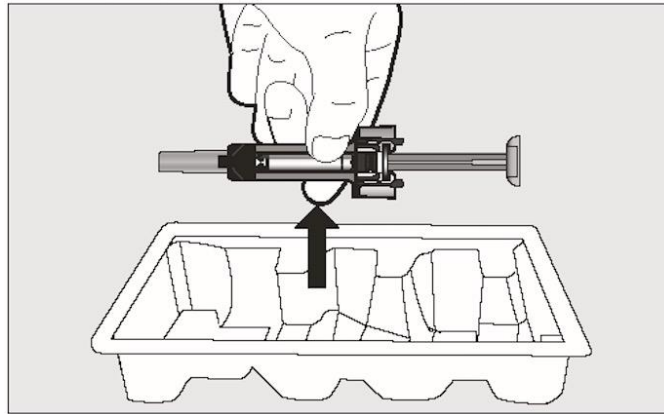


- Check the expiration date on the blister pack.
- **Do not** use it if the expiration date has passed.

If the expiration date has passed, safely throw away the prefilled syringe in a sharps disposal container (see **step 14**) and contact your healthcare provider.

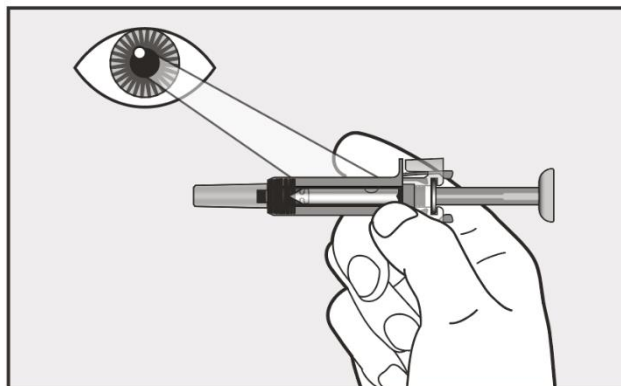
- Peel off the blister pack cover fully. Be careful when taking out the prefilled syringe.
- **Do not** flip the blister pack upside down to take out the prefilled syringe. This may damage the prefilled syringe.
- Take the prefilled syringe out of the blister pack by holding the middle part of the prefilled syringe. When holding the prefilled syringe, make sure you always hold the prefilled syringe as shown. **Do not** touch the needle-shield wings (see “**Prefilled Syringe Parts**”).
- **Do not** handle the prefilled syringe by holding the plunger or needle cap.

## Preparing for the Injection



### 5 Inspect the prefilled syringe closely.

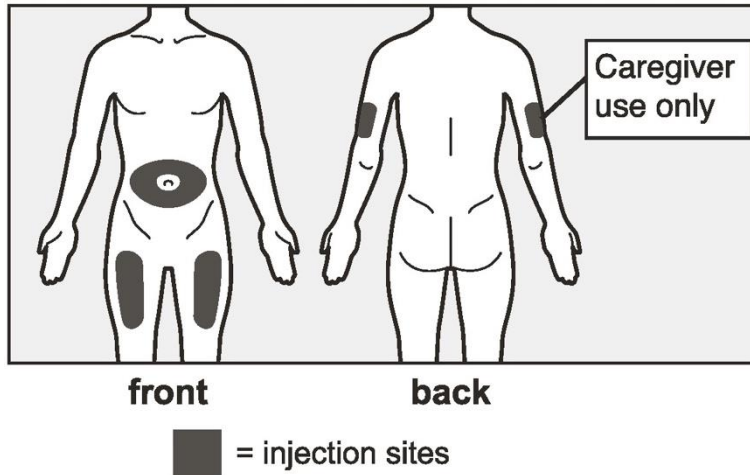
- Check the prefilled syringe. The medicine in the prefilled syringe should be clear and colorless to pale brownish-yellow. **Do not** use the prefilled syringe if the medicine is cloudy, discolored, or contains particles.
- Check the expiration date on the prefilled syringe. **Do not** use the prefilled syringe if the expiration date has passed.
- If the medicine does not look as described or if the expiration date has passed, safely throw away the prefilled syringe in a sharps disposal container (see **step 14**) and contact your healthcare provider.
- **Do not** use if the packaging or prefilled syringe appears damaged, tampered with, or has been dropped.



## Preparing for the Injection

### 6 Choose an injection site.

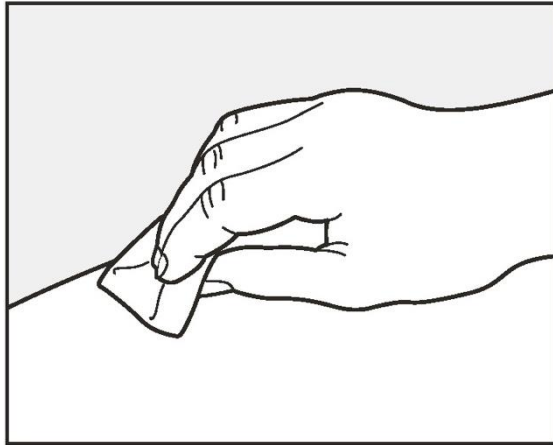
- If you are giving yourself the injection, you can inject into the front and middle of the thighs and the stomach area (abdomen). The outer area of the upper arms may also be used if the injection is being given by a caregiver. **Do not** try to inject into the upper arm area by yourself.
- **Do not** inject within the 2-inch area directly around your belly button (navel).
- **Do not** inject into moles, scars, bruises, or areas where the skin is tender, red, hard, or if there are breaks in the skin.
- **Do not** inject through clothing. The injection site should be exposed, clean skin.
- 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.



## Preparing for the Injection

**7 Wipe the injection site with an alcohol swab in a circular motion and let it air dry for 10 seconds.**

- **Do not** touch the injection site again before giving the injection.
- **Do not** fan or blow on the cleaned skin.

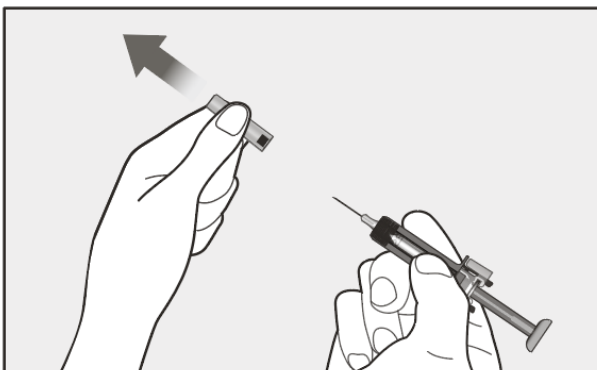


## Giving the Injection



**8 Hold the prefilled syringe firmly by the center with 1 hand and pull the needle cap straight off with your other hand.**

- **Do not** twist the needle cap.
- **Do not** hold, push or pull the plunger while you remove the needle cap.
- **Do not** touch the needle or let it touch any surfaces after removing the needle cap.
- Throw away the needle cap in regular household trash. **Do not** recap the needle.
- There may be 1 or more small air bubbles in the prefilled syringe. This is normal, and you should not try to remove the air bubbles.
- You may also see a drop of liquid at the end of the needle. This is also normal and will not affect the dose.

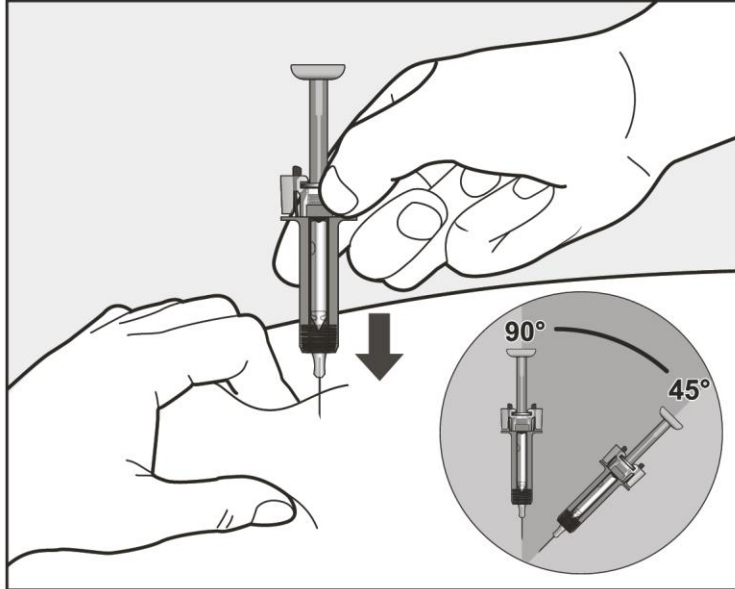


**9 Use your other hand and gently pinch the area of skin that was cleaned. Hold the pinched skin tight.**

- Pinching the skin is important to make sure that you inject under the skin (into the fatty area) but not any deeper (into muscle).

## Giving the Injection

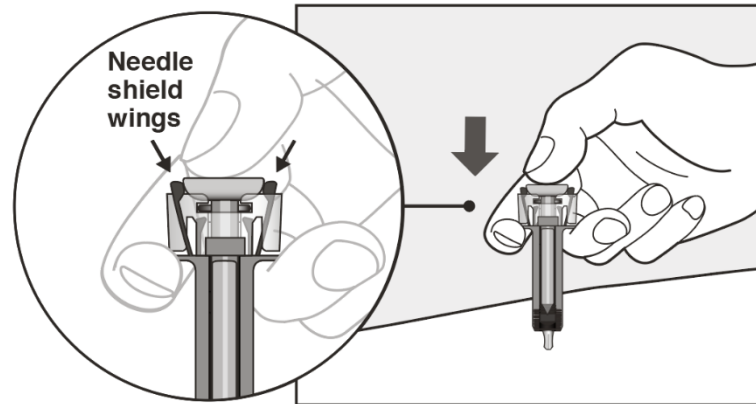
**10 Continue holding the prefilled syringe by the center and use a quick, dart-like motion to insert the needle all the way into the pinched skin at an angle between 45 degrees to 90 degrees as shown.**



- It is important to use the correct angle to make sure the medicine is delivered under the skin (into the fatty area), or the injection could be uncomfortable and the medicine may not work.
- **Do not** touch the plunger while inserting the needle into the skin.
- **Do not** insert the needle through clothing.
- Hold the prefilled syringe tightly in place and **do not** change the angle of injection or insert the needle again after the needle is inserted.
- You should not move and should avoid sudden movements when giving the injection.

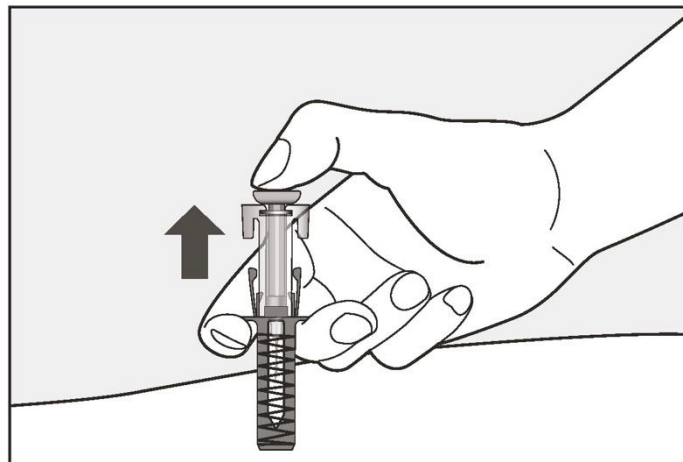
**11 Slowly inject all of the medicine by gently pushing the plunger all the way down until the needle-shield wings are pushed apart.**

- You must press the plunger all the way down to make sure that the full dose of medicine gets injected. If the plunger is not fully pressed, the needle-shield will not extend to cover the needle when it is removed.



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

- If the needle is not covered by the needle-shield, carefully remove the prefilled syringe from the skin and throw away the prefilled syringe in a sharps disposal container (see **step 14**).



## Giving the Injection

**13 There may be a little bleeding at the injection site. You can press a cotton ball or gauze over the injection site.**

- **Do not** rub the injection site.
- If needed, cover the injection site with a small bandage.
- In case of skin contact with the medicine, wash the area that touched the medicine with water.

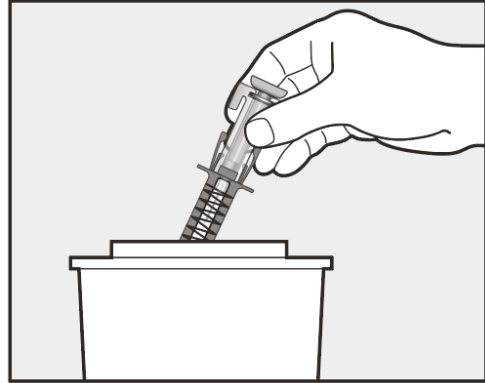
### **If your prescribed dose requires more than 1 injection:**

- Throw away the used prefilled syringe as described in **step 14**.
- Repeat **step 2** through **step 13** for the next injection using a new prefilled syringe.
- Choose a different injection site for each new injection at least 1 inch from other injection sites.
- Complete all the required injections for your prescribed dose, immediately one after another. Contact your healthcare provider if you have any questions.

## After the Injection

### 14 Throw away (dispose of) your used XOLAIR prefilled syringes in an FDA-cleared sharps disposal container right away after use.

- The XOLAIR prefilled syringe is a single-dose prefilled syringe and should not be used again.
- **Do not** throw away prefilled syringes in your household trash.
- **Do not** recap the needle.



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

- made of a heavy-duty plastic,
- can be closed 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 your sharps disposal container. There may be state or local laws about how you should throw away used prefilled 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** dispose of your used sharps disposal container in your household trash unless your community guidelines permit this.
- **Do not** recycle your used sharps disposal container.

Manufactured by:

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

Approved: April 2021