

# Arcalyst<sup>®</sup>

(rilonacept) For Injection

## HOW TO USE GUIDE



# Step-by-step instructions for self-administration

Setting up for the injection

Preparing the injection

Giving the injection

## USING ARCALYST

This guide is designed to help you understand the 3 steps for injecting ARCALYST:

STEP 1

**Setting up for the injection**

STEP 2

**Preparing the injection**

STEP 3

**Giving the injection**



Scan code to watch the full injection training video or visit [ARCALYST.com](https://www.arcalyst.com)

Refer to the ARCALYST Instructions for Use at [ARCALYST.com/PI](https://www.arcalyst.com/PI)

## STORING ARCALYST



Keep ARCALYST in the carton it comes in to protect from light



46°F  
36°F

Store ARCALYST in the refrigerator between 36°F and 46°F (2°C to 8°C). Call your pharmacy if you have any questions



Refrigerated ARCALYST can be used until the expiration date printed on the vial and carton



ARCALYST may be kept at room temperature after mixing. Use within **3 hours** of mixing

**ARCALYST is a subcutaneous injection.**

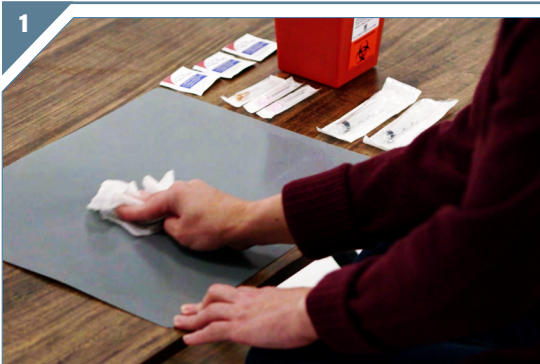
**Keep ARCALYST, injection supplies, and all other medicines out of reach of children.**

**It is important that you read, understand, and follow these instructions before using ARCALYST so that you prepare and inject the medicine the right way.**

**Do not try to inject ARCALYST until you have been shown the right way to give the injections by a healthcare professional.**

**STEP 1**

# Setting up for the injection



Choose a table or other flat area to set up the supplies for your injection.

Be sure the area is clean or clean it with an antiseptic or soap and water.



Wash your hands well with soap and water for about **20 seconds** and dry with a clean towel.

## 3

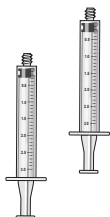
Put the following supplies on the cleaned area for each injection:



- 1 vial of ARCALYST (powder for mixing)



- 1 vial of preservative-free Sterile Water for Injection



- 2 sterile, 3-milliliter (mL) disposable syringes with markings at each 0.1 mL
  - 1 syringe for mixing ARCALYST
  - 1 syringe for injection



- 2 sterile disposable 18-gauge needles (1-inch, or 1½-inch) and 1 sterile 26-gauge disposable needle (½-inch) with needle covers
  - An 18-gauge needle for transferring the sterile water to the ARCALYST vial
  - An 18-gauge needle for withdrawing the reconstituted solution
  - A 26-gauge needle for injection



- 4 alcohol wipes



- 1 gauze pad



- 1 sharps disposal container for throwing away (disposing of) used needles, syringes, and vials

## IMPORTANT NOTES

**Check the expiration date on the following supplies:**

- |  |  |
|--|--|
| <input type="checkbox"/> Vial of ARCALYST                    | <input type="checkbox"/> Sterile disposable syringes |
| <input type="checkbox"/> Vial of Sterile Water for Injection | <input type="checkbox"/> Sterile disposable needles  |

**If the expiration date has passed on any of these supplies, do not use.  
Contact your pharmacy if the expiration date has passed.**



Do not use Sterile Water for Injection, syringes, or needles other than those provided by your pharmacy. Contact your pharmacy if you need replacement syringes or needles.



Do not touch the needles or the rubber stoppers on the vials with your hands. If you touch the rubber stopper, clean it with a new alcohol wipe.



If you touch a needle or the needle touches any surface, throw away the entire syringe in the sharps disposal container and use a new syringe.



**Do not reuse needles or syringes.**



To protect yourself and others from possible needlesticks, it is very important to throw away each syringe with the needle attached in the sharps disposal container right after use.

**STEP 2**

# Preparing the injection

**A: Preparing the vials**

**B: Mixing ARCALYST**

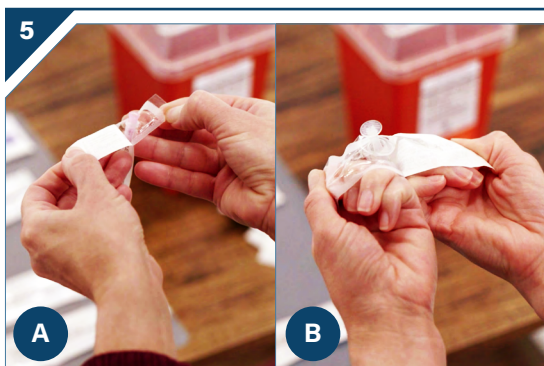
**C: Preparing the dose**

## A: Preparing the vials



Remove the protective plastic caps from both vials.

Clean the top of each vial with an alcohol wipe. Use one wipe for each vial and wipe in one direction around the top of the vial.



Open the wrapper that contains one of the 18-gauge needles by pulling apart the tabs and place it on the cleaned surface area. See Picture 5A.

**Do not remove the needle cover. This needle will be used to mix the water with ARCALYST powder in the vial.**

Open the wrapper that contains the syringe by pulling apart the tabs. See Picture 5B.



6



Hold the barrel of the syringe with one hand and use your other hand to twist the 18-gauge needle with cover onto the tip of the syringe until it fits firmly.

7



Hold the syringe upright at eye level.

With the needle cover still on the 18-gauge needle, pull back the plunger to the 2.3 mL mark to fill the syringe with air.

8



Hold the syringe in one hand and use the other hand to pull the needle cover straight off.

**Do not twist the needle as you pull off the cover. Place the needle cover aside.**

9



Hold the syringe in the hand that you will use to mix your medicine. Hold the Sterile Water for Injection vial on a firm surface with your other hand.

Slowly insert the needle straight through the rubber stopper. **Do not bend the needle.**

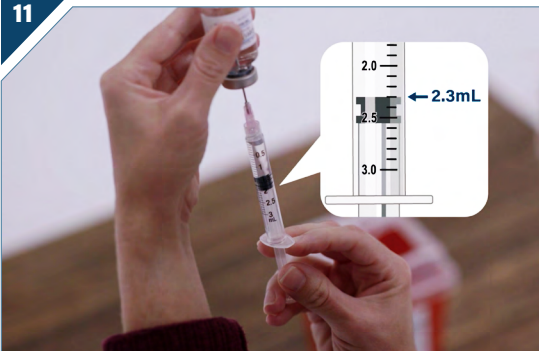
Push the plunger in all the way to push the air into the vial.

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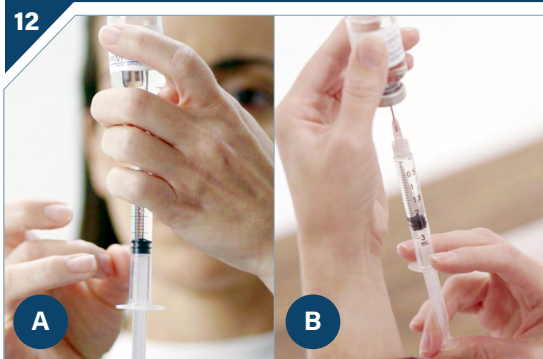


Hold the vial in one hand and the syringe in the other hand and carefully turn the vial upside down so that the needle is pointing straight up.

11



Make sure the tip of the needle is covered by the liquid and slowly pull back on the plunger to the 2.3 mL mark to withdraw the Sterile Water for Injection from the vial.

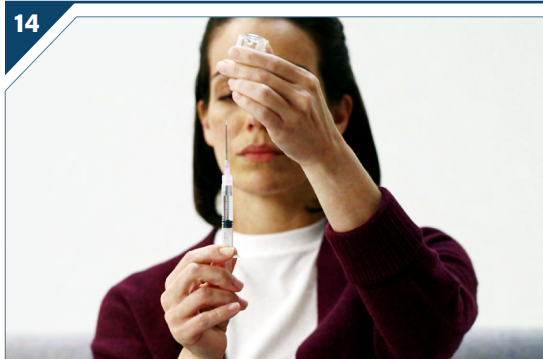


Keep the vial upside down and gently tap the syringe with your fingers until any air bubbles rise to the top of the syringe. See Picture 12A.

To remove the air bubbles, gently push in the plunger so only the air is pushed out of the syringe and back into the bottle. See Picture 12B.



After removing the air bubbles, check the syringe to be sure that the right amount of Sterile Water for Injection has been drawn into the syringe.

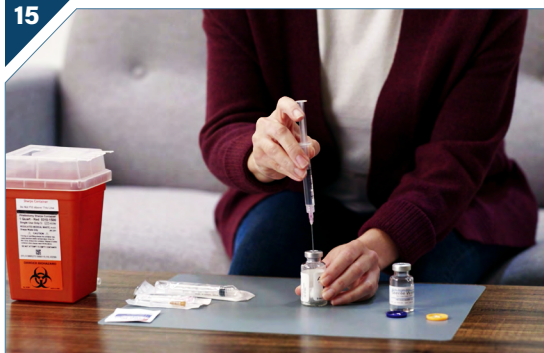


Carefully remove the syringe with the 18-gauge needle from the Sterile Water for Injection vial.

**Do not touch the needle.**

## B: Mixing ARCALYST

15



With one hand, hold the ARCALYST vial on a firm surface.

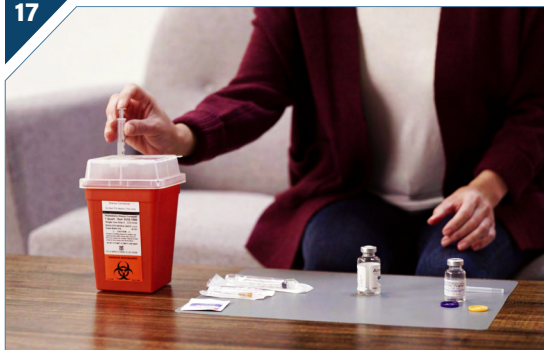
With the other hand, take the syringe with the 18-gauge needle that contains the Sterile Water for Injection and slowly insert the needle straight down through the rubber stopper of the ARCALYST vial.

16



Gently push the plunger in all the way to inject the Sterile Water for Injection into the vial, aiming the stream of Sterile Water for Injection down the side of the vial into the powder.

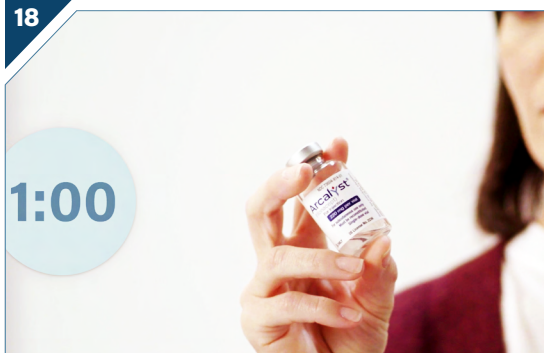
17



Remove the syringe and needle from the rubber stopper and throw away the needle, syringe, and Sterile Water for Injection vial in the sharps disposal container.

**Do not try to put the needle cover back on the needle.**

18



Hold the vial containing the ARCALYST and Sterile Water for Injection sideways (not upright) with your thumb on the bottom and your fingers around the neck of the vial (not touching the rubber stopper).

**Quickly shake the vial back and forth (side to side) for about 1 minute.**

19



Put the vial back on the table and let the vial sit for about **1 minute**.

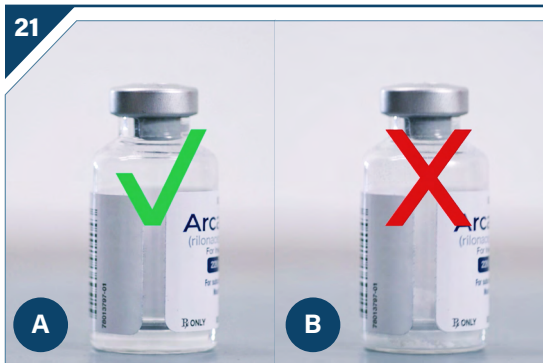
Check the vial for any particles or clumps of powder that have not dissolved.



If the powder has not completely dissolved, shake the vial quickly back and forth for 30 seconds more. See Picture 20A.

Let the vial sit for about 1 minute. See Picture 20B.

**Repeat this step until the powder is completely dissolved and the solution is clear.**



The mixed ARCALYST should be thick, clear, and colorless to pale yellow. See Picture 21A.

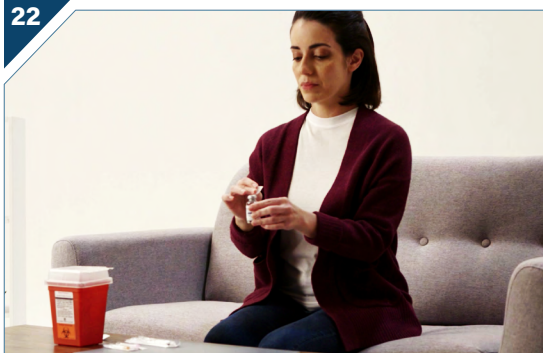
**Do not use the mixed liquid if it is discolored or cloudy, or if particles are in it.** See Picture 21B.

**Note: Contact your pharmacy to report any mixed ARCALYST that is discolored, cloudy, or contains particles.**

**Reminder: ARCALYST may be kept at room temperature after mixing. Use within 3 hours of mixing. Keep ARCALYST away from light.**

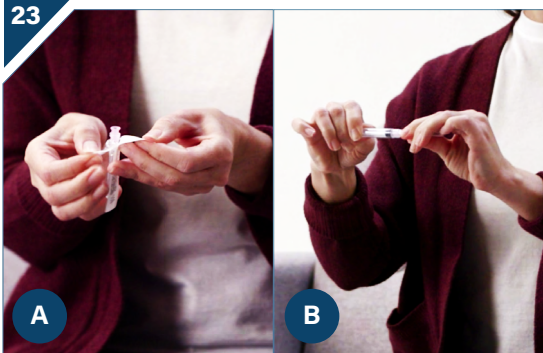
## C: Preparing the dose

22



Hold the ARCALYST vial in one hand and wipe the top of the ARCALYST vial in 1 direction with a new alcohol wipe with the other hand.

23



Take a new sterile, disposable 18-gauge needle (see Picture 23A) and attach it firmly to a new syringe (see Picture 23B) without removing the needle cover.

24

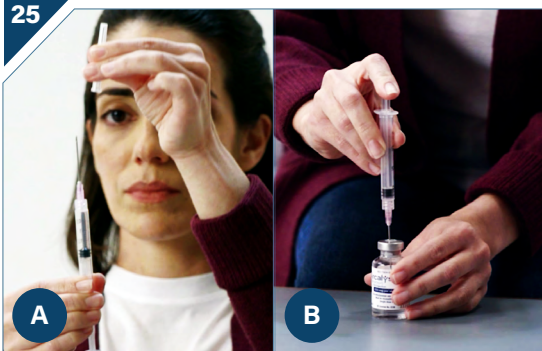


To draw air into the syringe, hold the syringe upright at eye level.

**Do not remove the needle cover.**

Pull back the plunger on the syringe to the mark that is equal to the amount of mixed ARCALYST that your healthcare provider has prescribed for you to inject.

25



Remove the needle cover by pulling straight up without twisting the needle. Place the needle cover aside and be careful not to touch the needle. See Picture **25A**.

Keep the ARCALYST vial on a flat firm surface and slowly insert the needle straight down through the rubber stopper.

Push the plunger down and inject all of the air into the vial. See Picture **25B**.

26



Hold the vial in one hand and the syringe in the other hand and carefully turn the vial upside down so that the needle is pointing straight up.

Hold the vial at eye level.



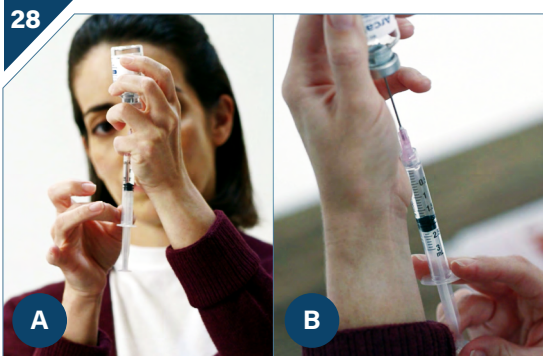
27



Keep the tip of the needle in the liquid and slowly pull back on the plunger to the mark on the syringe that matches the amount of medicine prescribed by your healthcare provider.

**Note:** The maximum amount of medicine that you can withdraw from 1 vial of ARCALYST is 2 mL. If the amount of medicine you need to withdraw for you or your child's dose is more than 2 mL, you will need to use 2 vials. The healthcare provider will tell you the right amount of medicine to withdraw from the 2 vials and how to give the 2 injections. **Always use new syringes and needles for each injection.**

28



Keep the vial upside down with the needle straight up, and gently tap the syringe until any air bubbles rise to the top of the syringe. See Picture 28A.

**It is important to remove air bubbles so that you withdraw the right amount of medicine from the vial.**

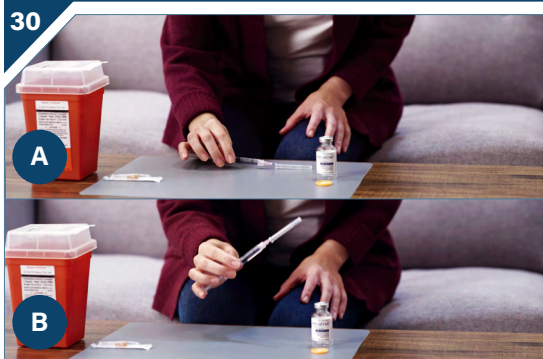
To remove the air bubbles, gently push in the plunger so only the air is pushed out of the syringe and back into the bottle. See Picture 28B.

29



Check to make sure that you have the amount of medicine prescribed by your healthcare provider in the syringe.

Remove the syringe with the needle from the vial.



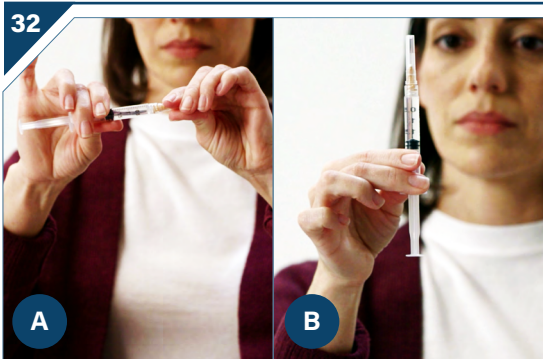
You will now prepare to switch needles.

To remove the 18-gauge needle and replace it with the new 26-gauge needle for injection, first **use one hand** to slide the needle into the needle cap (see Picture 30A) and **scoop upwards** to cover the needle. See Picture 30B.



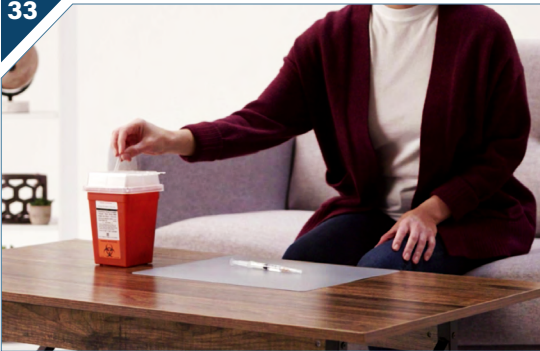
When the needle is covered, push the needle cap toward the syringe to fully attach it **with one hand** to prevent an accidental stick with the needle. See Picture 31A.

Twist off and remove the 18-gauge needle with the needle cap. See Picture 31B.



Open a new sterile, disposable 26-gauge needle and attach securely to the syringe (see Picture 32A) without removing the needle cover (see Picture 32B).

33



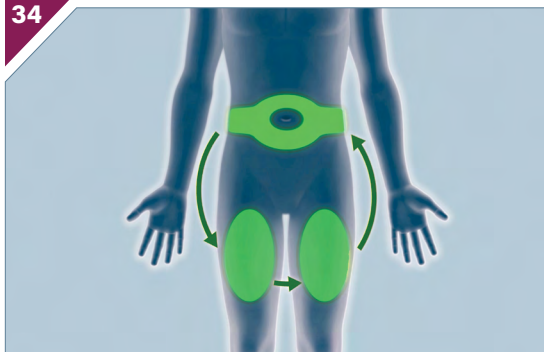
Throw away in the sharps disposal container both the ARCALYST vial, even if there is medicine left in the vial, and the 18-gauge needle that still has the needle cover attached to it.

**Do not use any vial of ARCALYST more than 1 time.**

**STEP 3**

# Giving the injection

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ARCALYST is given by injection into the tissue directly under the skin (subcutaneous injection).

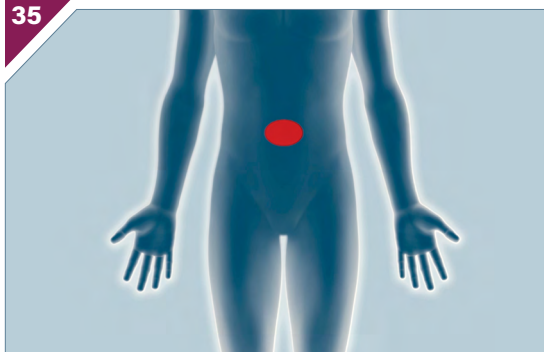
**You should change (rotate) the injection site each time you inject ARCALYST.**

If you need to use 2 vials and give 2 injections for your or your child's prescribed dose of ARCALYST, you should use 2 different injection sites.

Changing injection sites helps to prevent irritation and allows the medicine to be completely absorbed.

Ask your or your child's healthcare provider if you have any questions about changing injection sites.

35



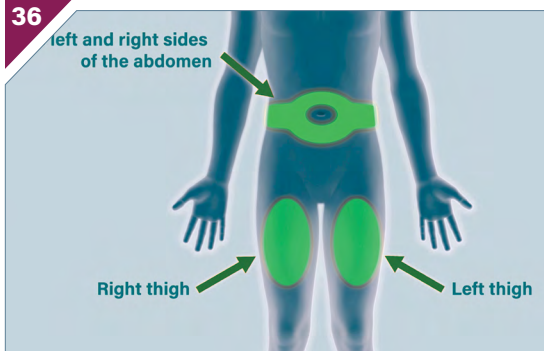
**Do not inject ARCALYST into any muscle, vein, or artery.**

**Do not inject within a 2-inch area around the belly button.**

**Do not inject into skin that is tender, red, or hard.** If an area is tender or feels hardened, choose another site for injection until the tenderness or hardening goes away.

Tell your healthcare provider about any skin reactions including redness, swelling, or hardening of the skin.

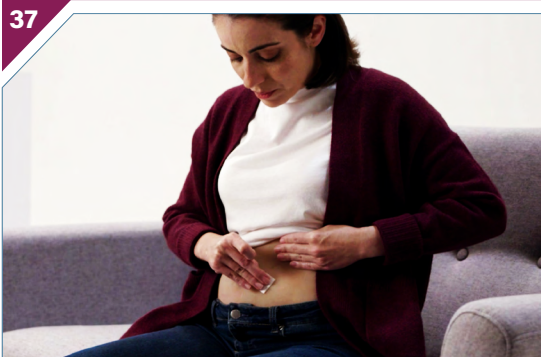
36



Areas where you may inject ARCALYST include the:

- Left and right sides of the abdomen
- Left and right thighs

If someone else is giving the injection, the upper left and right arms may also be used for injection.



Choose the area for the injection.

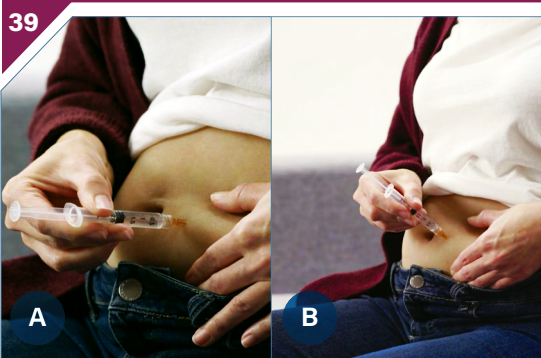
Clean the area in a circular motion with a new alcohol wipe. Begin at the center of the injection site and move outward.

Let the alcohol air dry completely.



Remove the needle cover and hold the syringe in one hand like you would hold a pencil.

With the other hand gently pinch a fold of skin at the cleaned injection site.



Use a quick dart-like motion to insert the needle straight into the skin at a 90-degree angle. See Picture **39A**.

**Do not push down on the plunger while inserting the needle into the skin.**

For small children or people with little fat under the skin, you may need to hold the syringe and needle at a 45-degree angle. See Picture **39B**.

40



After the needle is completely in the skin, let go of the pinched skin.

With your free hand, hold the syringe near the bottom. Gently pull back the plunger with the other hand.

41



If blood comes into the syringe, the needle has entered a blood vessel. You will have to restart the injection process from the beginning.

Remove the needle and throw away the syringe and needle in the sharps disposal container.

Start over with “**Step 1: Setting up for the injection**” using new supplies (syringes, needles, vials, alcohol swabs, and gauze pad) and new vials of ARCALYST and Sterile Water for Injection.

42



If no blood comes into the syringe, inject all the medicine in the syringe at a slow, steady rate, pushing the plunger all the way down.

It may take up to 30 seconds to inject the entire dose.

43



Pull the needle out of the skin and hold a gauze pad over the injection site for several seconds.

**Do not replace the needle cover.**

**Throw away used alcohol wipes in the household trash.**

**Do not throw away vials, needles, or syringes in the household trash or recycle bin.**

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Throw away the vials, used syringes, and needles in a sharps disposal container. If you do not have a 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
- Properly labeled to warn of hazardous waste inside the container



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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 needles and syringes.

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

- **Do not reuse or share your syringes with other people**
- **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**
- **Keep the sharps disposal container out of the reach of children**

## INJECTION SUPPORT



Contact your healthcare provider immediately if you have any concerns about your or your child's treatment



Contact your pharmacy for assistance with injection supplies

KINIKSA  
**oneconnect**<sup>™</sup>

**Your personalized  
treatment support  
starts here**

# We're here to help

**Reach out to the Kiniksa OneConnect<sup>™</sup> patient support program team with any additional questions you may have about your treatment.**

Your dedicated Patient Access Lead is here to provide personalized one-on-one support every step of the way.



**[KiniksaOneConnect@kiniksa.com](mailto:KiniksaOneConnect@kiniksa.com)**



**1-833-KINIKSA** (1-833-546-4572)  
Monday-Friday (7 AM - 7 PM ET)



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(riloncept) For Injection