

Instructions for Use
ARCALYST® (ARK-a-list)
(rilonacept)
For Injection
For Subcutaneous Use

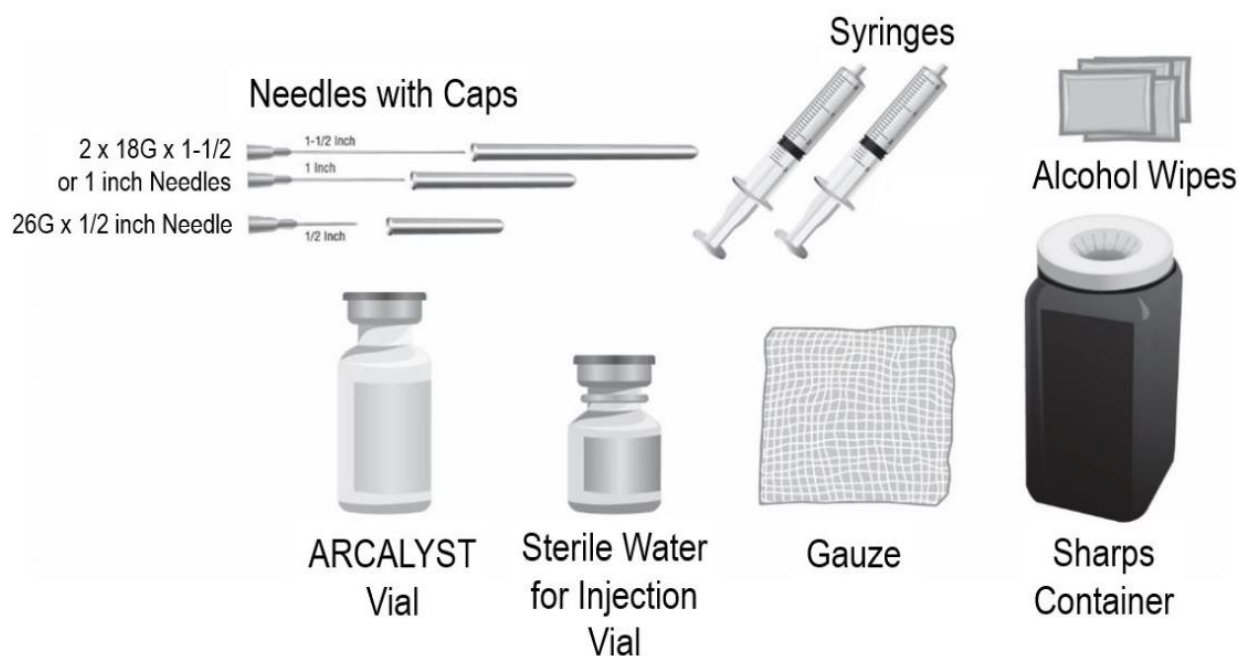
It is important that you read, understand, and follow these instructions before you or your child start using ARCALYST so that you prepare and inject the medicine the right way.

Do not try to inject ARCALYST until you have been shown the right way to give the injections by your or your child's healthcare provider.

How do I prepare and give an ARCALYST injection?

Step 1: Setting up for an injection

1. 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.
2. Wash your hands well with soap and water about 20 seconds, and dry with a clean towel.
3. Put the following supplies on the cleaned area for each injection (see Figure A):



Supplies needed to give your ARCALYST injection:

- 1 vial of ARCALYST (powder for mixing)

Additional supplies needed (available from the pharmacy):

- 1 vial of preservative-free Sterile Water for Injection, USP
- 2 sterile, 3-milliliter (mL) disposable syringes with markings at each 0.1 mL (see Figure B):
 - 1 syringe for mixing ARCALYST
 - 1 syringe for injection

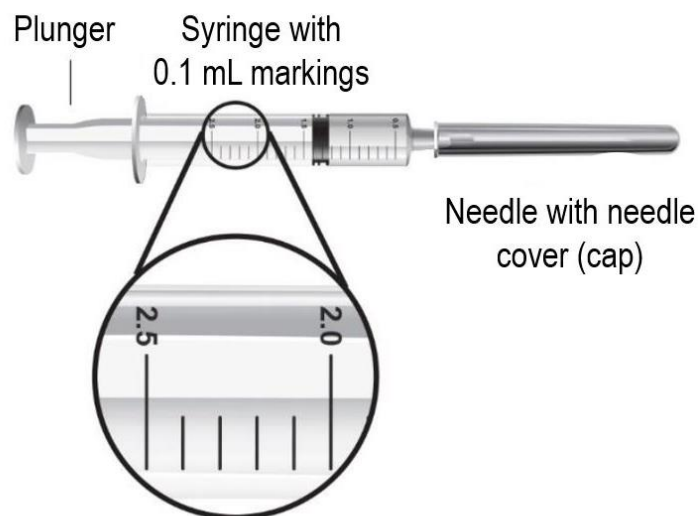


Figure B

- 2 sterile disposable needles (18-gauge, 1-inch or 1½-inch) and 1 sterile disposable needle (26-gauge, ½-inch) with needle covers
 - 1 18-gauge needle for transferring the Sterile Water for Injection, USP, to the ARCALYST vial
 - 1 18-gauge needle for withdrawing the mixed solution
 - 1 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

Note:

- Do not use Sterile Water for Injection, USP, 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 vials

1. Check the expiration date on the carton or on the vial of ARCALYST. Do not use the vial if the expiration date has passed. Contact your pharmacy if the expiration date has passed.
2. Check the expiration date on the vial of Sterile Water for Injection, USP. Do not use the vial if the expiration date has passed. Contact your pharmacy for assistance.

3. Remove the protective plastic caps from both vials.
4. Clean the top of each vial with an alcohol wipe. Use 1 wipe for each vial and wipe in 1 direction around the top of the vial (see Figure C).

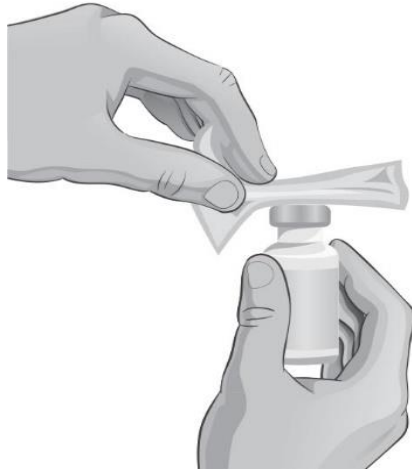


Figure C

5. Check the expiration date on the needle. Do not use the needle if the expiration date has passed. Contact your pharmacy if the expiration date has passed.
6. Open the wrapper that contains 1 of the 18-gauge needles by pulling apart the tabs and set it aside for later use. Do not remove the needle cover. This needle will be used to mix the water with ARCALYST powder in the vial.
7. Check the expiration date on the syringe. Do not use the syringe if the expiration date has passed. Contact your pharmacy if the expiration date has passed.
8. Open the wrapper that contains the syringe by pulling apart the tabs (see Figure D).

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

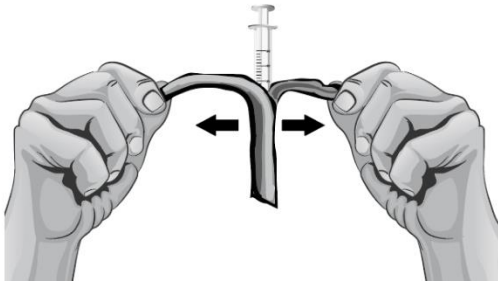


Figure D

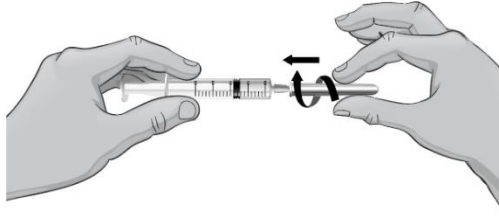


Figure E

10. 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 (see Figure F).

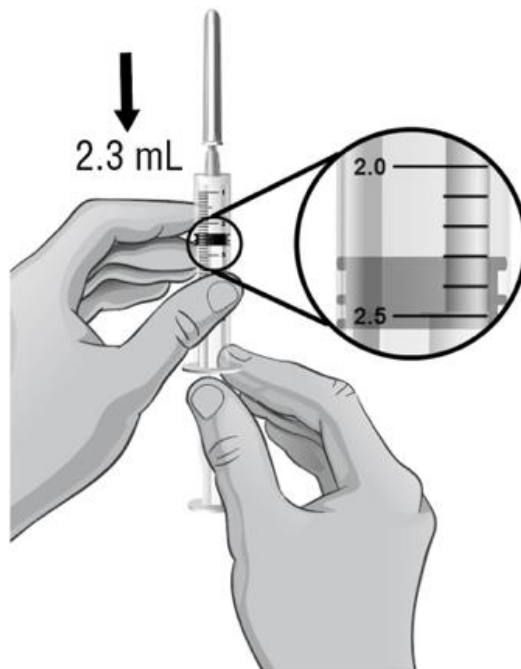


Figure F

11. 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. Hold the syringe in the hand that you will use to mix your medicine. Hold the Sterile Water for Injection, USP, 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 (see Figure G).

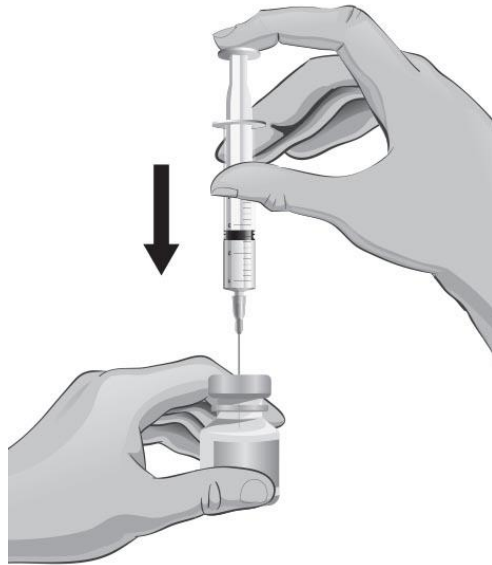


Figure G

12. 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 (see Figure H).
13. 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, USP, from the vial (see Figure H).

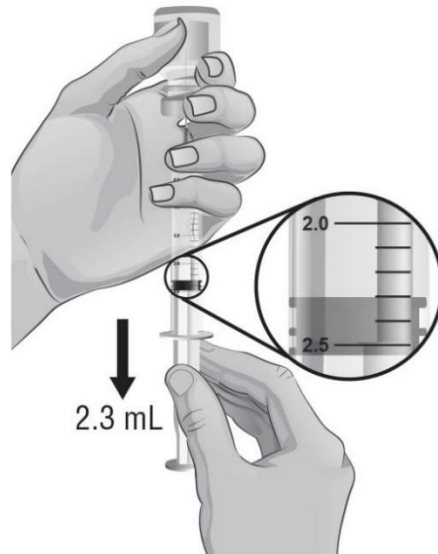


Figure H

14. Keep the vial upside down and gently tap the syringe with your fingers until any air bubbles rise to the top of the syringe.
15. 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.
16. After removing the air bubbles, check the syringe to be sure that the right amount of Sterile Water for Injection, USP, has been drawn into the syringe (see Figure I).

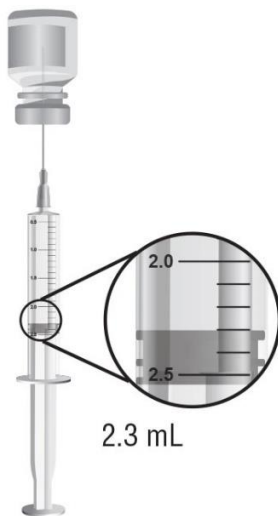


Figure I

17. Carefully remove the syringe with the 18-gauge needle from the Sterile Water for Injection, USP, vial. Do not touch the needle.

Step 3: Mixing ARCALYST

18. With one hand, hold the ARCALYST vial on a firm surface.
19. With the other hand, take the syringe with the 18-gauge needle that contains the Sterile Water for Injection, USP, and slowly insert the needle straight down through the rubber stopper of the ARCALYST vial.
20. Gently push the plunger in all the way to inject the Sterile Water for Injection, USP, into the vial, aiming the stream of Sterile Water for Injection, USP, down the side of the vial into the powder (see Figure J).

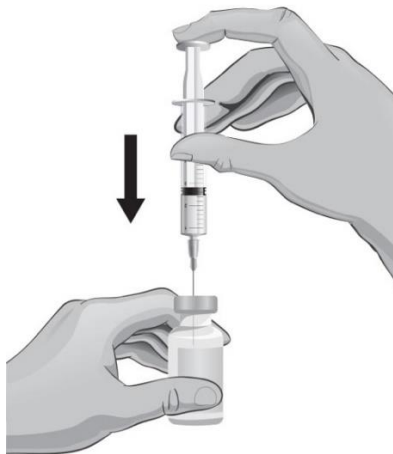


Figure J

21. Remove the syringe and needle from the rubber stopper and throw away the needle, syringe, and Sterile Water for Injection, USP, vial in the sharps disposal container. Do not try to put the needle cover back on the needle (see Figure K).



Figure K

22. Hold the vial containing the ARCALYST and Sterile Water for Injection, USP, sideways (not upright) as shown (see Figure L). Do not touch the rubber stopper. Quickly shake the vial back and forth (side-to-side) for about 1 minute.



Figure L

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

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

25. If the powder has not completely dissolved, shake the vial quickly back and forth for 30 seconds more. Let the vial sit for about 1 minute.

26. Repeat Step 25 until the powder is completely dissolved and the solution is clear (see Figure M).



Figure M

27. The mixed ARCALYST should be thick, clear, and colorless to pale yellow. Do not use the mixed liquid if it is discolored or cloudy, or if particles are in it.

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

28. ARCALYST may be kept at room temperature after mixing. ARCALYST should be used within **3 hours** of mixing. Keep ARCALYST away from light.

Step 4: Preparing the Injection

29. Hold the ARCALYST vial in one hand and wipe in 1 direction around the top of the ARCALYST vial with a new alcohol wipe with the other hand (see Figure N).



Figure N

30. Take a new sterile, disposable 18-gauge needle and attach it firmly to a new syringe without removing the needle cover (see Figures O and P).

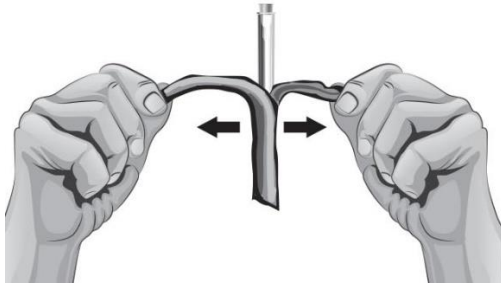


Figure O

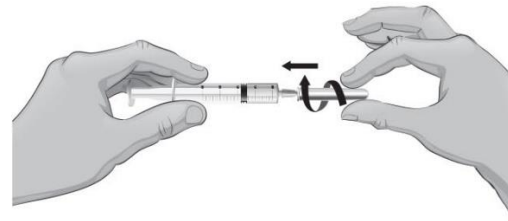


Figure P

31. 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 the healthcare provider has prescribed for you to inject (see Figure Q).

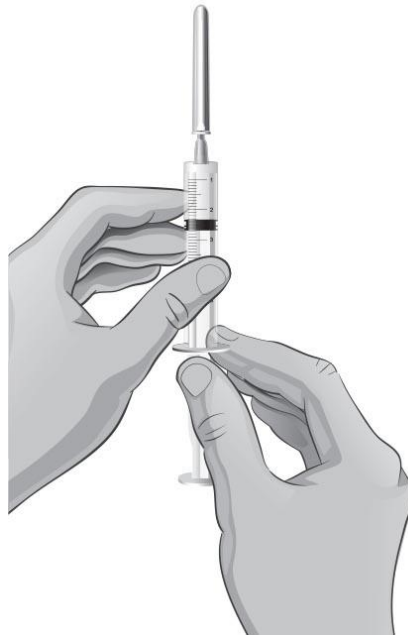


Figure Q

32. 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 and be careful not to touch the needle. 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 Figure R).

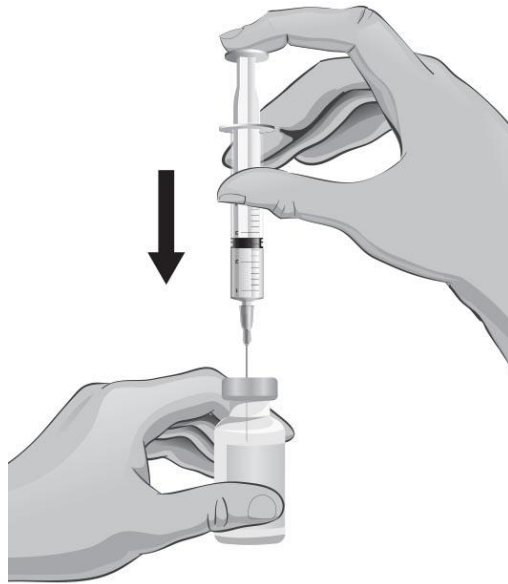


Figure R

33. 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.
34. 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 or your child's healthcare provider (see Figure S).



Figure S

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 your or your child's dose of ARCALYST 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.**

35. 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 Figure T).

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



Figure T

36. To remove the air bubbles, slowly and gently push in the plunger so only the air is pushed through the needle.
37. Check to make sure that you have the amount of medicine prescribed by the healthcare provider in the syringe. Remove the syringe with the needle from the vial.
38. **You will now prepare to switch needles.**
39. To remove the 18-gauge needle and replace it with the new 26-gauge needle for injection, place the syringe with the 18-gauge needle and the needle cap on a flat surface. **Use one hand** to slide the 18-gauge needle into the needle cap and **scoop upwards** to cover the needle (see Figure U1).
40. 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 Figure U2). Twist off and remove the 18-gauge needle with the needle cap (see Figures U3 and U4).

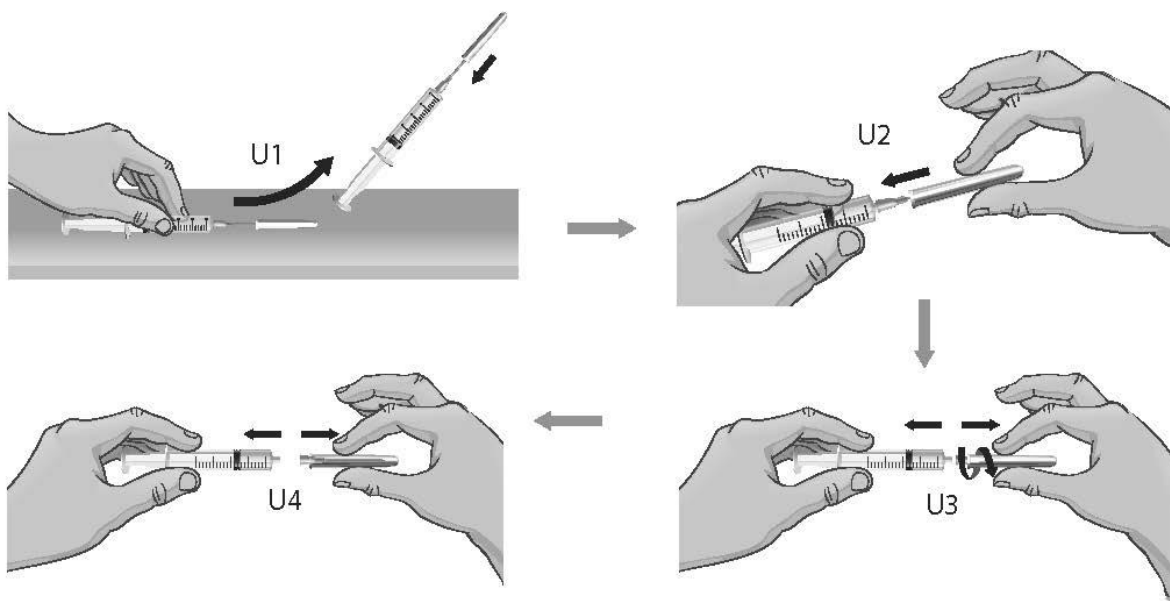


Figure U

41. Open a new sterile, disposable 26-gauge needle (see Figure V) and attach securely to the syringe without removing the needle cover (see Figure W).

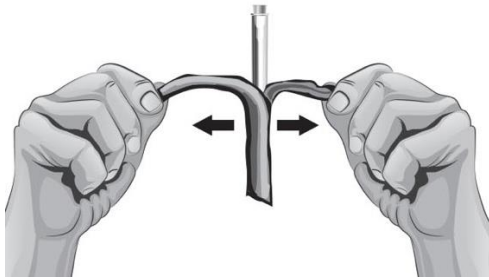


Figure V

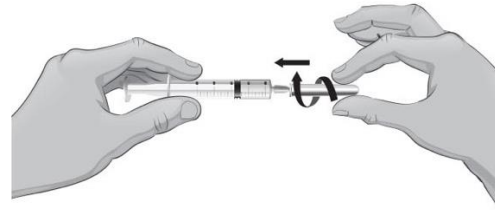


Figure W

42. Throw away the ARCALYST vial and 18-gauge needle that still has the needle cover attached to it in the sharps disposal container even if there is medicine left in the vial (see Figure X). Do not use any vial of ARCALYST more than 1 time.



Figure X

Step 5: Giving the Injection

43. ARCALYST is given by injection into the tissue directly under the skin (subcutaneous injection). Do not inject ARCALYST into any muscle, vein, or artery.

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.

- 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 or your child's healthcare provider about any skin reactions including redness, swelling, or hardening of the skin.
- Areas where you may inject ARCALYST include the left and right sides of the abdomen, and the left and right thighs. If you are giving the injection to your child or someone else, the upper left and right arms may also be used for injection (see Figure Y):

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

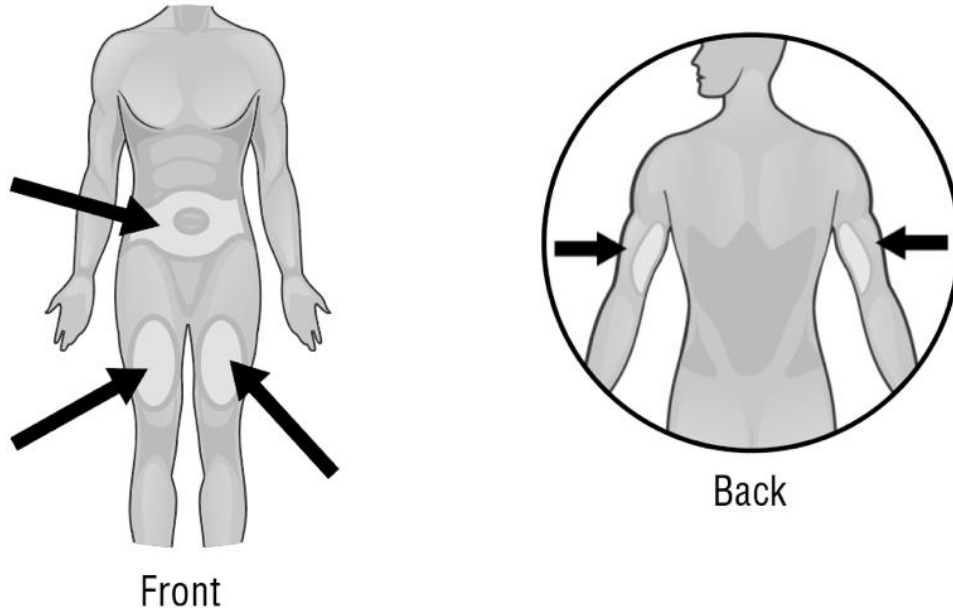


Figure Y

44. 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.
45. Remove the needle cover and hold the syringe in one hand like you would hold a pencil.
46. With the other hand, gently pinch a fold of skin at the cleaned injection site (see Figure Z).

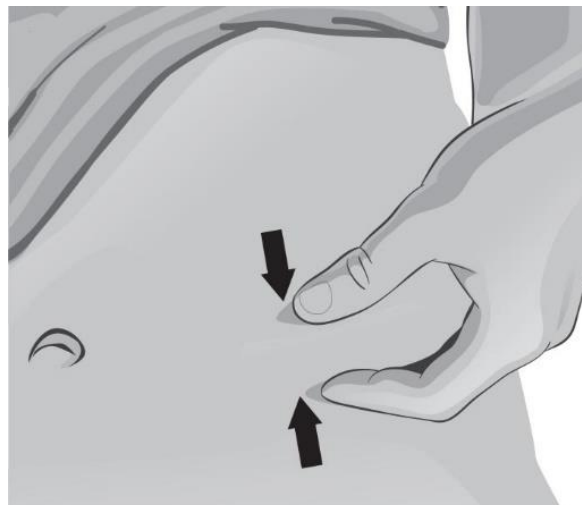


Figure Z

47. Use a quick “dart like” motion to insert the needle straight into the skin at a 90-degree angle (see Figure AA). 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 Figure BB).

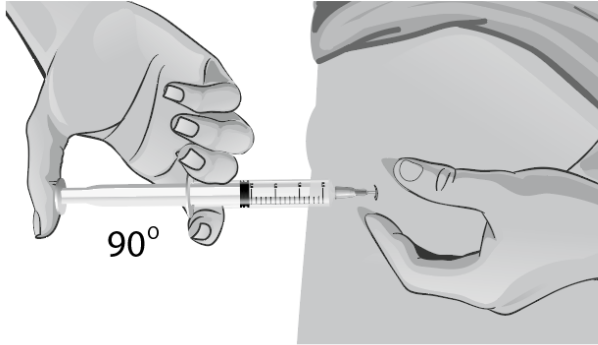


Figure AA

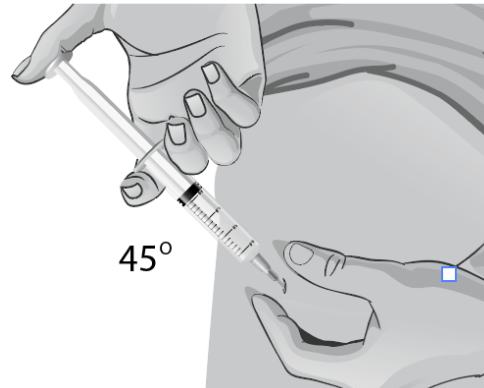


Figure BB

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

49. With your free hand, hold the syringe near the bottom. Gently pull back the plunger. If blood comes into the syringe, the needle has entered a blood vessel. Remove the needle and throw away (discard) the syringe and needle in the sharps disposal container. Start over with “**Step 1: Setting up for an injection**” using new supplies (syringes, needles, alcohol swabs, gauze pad, and new vials of ARCALYST and Sterile Water for Injection, USP).

50. 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.

51. Pull the needle out of the skin and hold a gauze pad over the injection site for several seconds (see Figure CC).

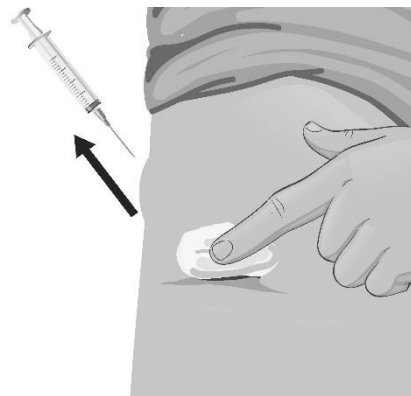


Figure CC

52. Do not replace the needle cover. Throw away the vials, used syringes and needles in an FDA-cleared sharps disposal container (see Figure DD). **Do not** throw away vials, needles, or syringes in the household trash or recycle.

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.



Figure DD

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 that you live in, go to the FDA's 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.

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

54. Used alcohol wipes can be thrown away in the household trash.

Contact your or your child's healthcare provider right away with any questions or concerns about ARCALYST.



Manufactured by:

Kiniksa Pharmaceuticals (UK), Ltd., London, UK W1S 4PZ

U.S. License Number 2236

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For more information about ARCALYST, call 1-833-KINIKSA (1-833-546-4572), or visit www.ARCALYST.com.

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

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