

Patient Information
SAJAZIR™ (Sah ja' zeer)
(icatibant) Injection

Please read this Patient Information before you use SAJAZIR™ and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

What is SAJAZIR?

SAJAZIR is a medicine used to treat acute attacks of hereditary angioedema (HAE) in adults 18 years and older. It is not known if SAJAZIR is safe or effective for children under 18 years of age.

What should I tell my healthcare provider before taking SAJAZIR?

Before you use SAJAZIR, tell your healthcare provider if you:

- have any other medical conditions.
- are breastfeeding or plan to breastfeed. It is not known if SAJAZIR passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you use SAJAZIR.
- are pregnant or plan to become pregnant. It is not known if SAJAZIR will harm your unborn baby. You and your healthcare provider will decide if SAJAZIR is right for you.

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

How should I use SAJAZIR?

- Use SAJAZIR exactly as your healthcare provider tells you to use it.
- Your healthcare provider will prescribe the right dose of SAJAZIR for you and tell you when to use it.
- Your healthcare provider will teach you or a caregiver how to give SAJAZIR.
- Read the Instructions for Use at the end of the Patient Information for information about the right way to use SAJAZIR.
- If your symptoms continue or come back, you may repeat your SAJAZIR at least six hours apart.
- Do not use more than 3 doses in 24 hours.
- **If you have a laryngeal attack**, inject SAJAZIR and then go to the nearest hospital emergency room right away.

What should I avoid while using SAJAZIR?

Tiredness, drowsiness, and dizziness can occur in people who take SAJAZIR. If this occurs, do not drive a car, use machinery, or do anything that needs you to be alert.

What are the possible side effects of SAJAZIR?

The most common side effects of SAJAZIR include:

- redness, bruising, swelling, warmth, burning, itching, irritation, hives, numbness, pressure, or pain at the injection site
- fever
- too much of an enzyme called transaminase in your blood
- dizziness
- nausea
- headache
- rash

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of SAJAZIR. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store SAJAZIR?

- Store SAJAZIR between 36°F to 77°F (2°C to 25°C).
- Do not freeze.
- Store SAJAZIR in the original carton until you are ready to use it.

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

General information about the safe and effective use of SAJAZIR

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use SAJAZIR for a condition for which it was not prescribed. Do not give SAJAZIR to other people, even if they have the same symptoms that you have. It may harm them.

This Patient Information leaflet summarizes the most important information about SAJAZIR. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about SAJAZIR that is written for health professionals.

For more information, call 1-800-836-4380.

What are the ingredients in SAJAZIR?

Active ingredient: icatibant acetate

Inactive Ingredients: sodium chloride (isotonicity reagent), glacial acetic acid (pH adjuster), sodium hydroxide (pH adjuster), and water

Step-by-Step Instructions for your SAJAZIR injection

Step 1. Preparing your dose of SAJAZIR

- Wash your hands with soap and water.
- You will need the following supplies:
 - Your SAJAZIR carton that includes 1 single-dose SAJAZIR prefilled syringe and 1 needle.
 - An alcohol wipe
 - The medicine inside your SAJAZIR prefilled syringe should be clear and colorless. Do not use your SAJAZIR prefilled syringe if the solution contains particles, is cloudy, or an unusual color.

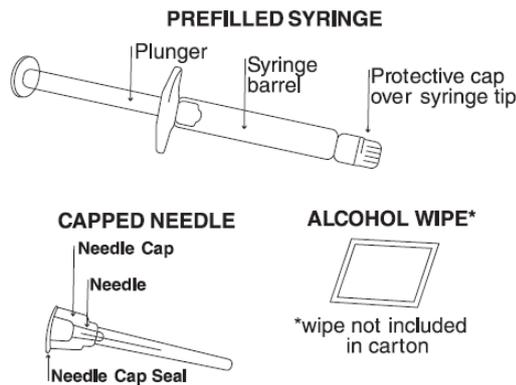


Figure A

Step 2. Remove the prefilled syringe and needle from the carton. See Figure B.

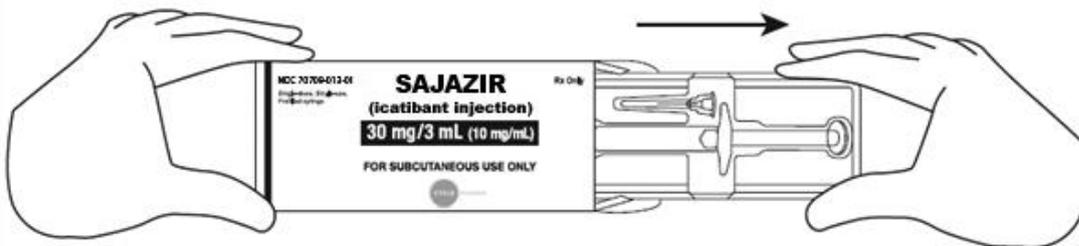


Figure B

Step 3. Remove the seal from the needle cap (the needle should remain inside the protective needle cap until ready to use). See Figure C.



Figure C

Step 4. Remove the protective cap from the end of the pre-filled syringe by unscrewing the cap. Hold the syringe firmly. Carefully attach the needle to the prefilled syringe containing the colorless SAJAZIR solution. See **Figure D**.

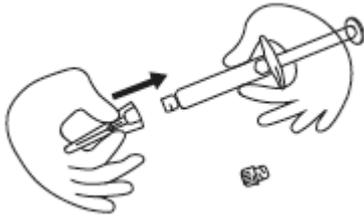


Figure D

Step 5. Firmly screw the needle on the prefilled syringe. Be careful not to remove the needle from the needle cap. See **Figure E**.

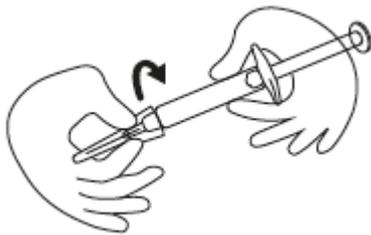


Figure E

Preparing the Injection Site

Step 6. Choose the injection site. The injection site should be a fold of skin on your stomach, about 2 to 4 inches (5 to 10 cm) below your belly button on either side. See **Figure F**.

The area you choose for injection should be at least 2 inches (5 cm) away from any scars. Do not choose an area that is bruised, swollen, or painful.

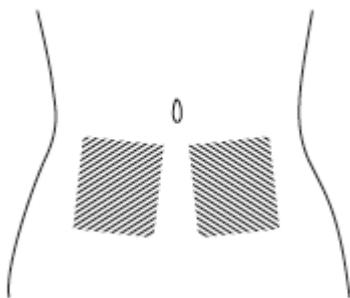


Figure F

Step 7. Clean your SAJAZIR site with an alcohol wipe and allow it to dry. See Figure G.

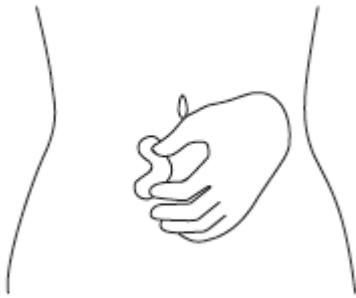


Figure G

Injecting your SAJAZIR

Step 8. Remove the needle from the needle cap by holding the needle cap and carefully pulling the syringe. Do not pull up on the plunger. See Figure H.

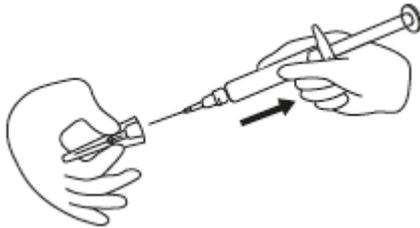


Figure H

Step 9. Hold the SAJAZIR prefilled syringe in 1 hand, between your fingers and thumb. See Figure I.

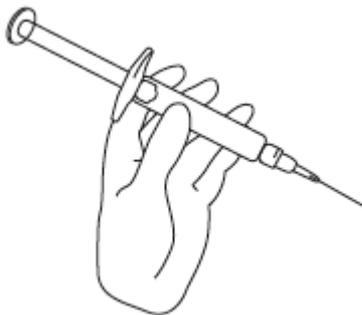


Figure I

Step 10. Use your other hand to gently pinch the fold of skin you cleaned with the alcohol wipe between your thumb and fingers for your injection. See Figure J.



Figure J

Step 11. Hold the syringe between a 45 to 90 degree angle to your skin with the needle facing the fold of skin you are holding. See Figure K.

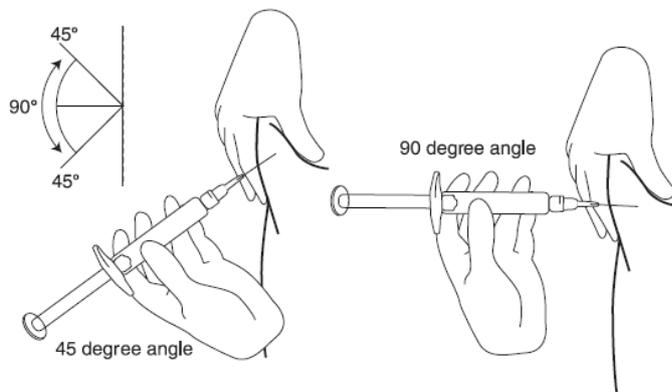


Figure K

Step 12. Hold the fold of skin. Bring the syringe to the skin and quickly insert the needle into the skin fold. See Figure L.



Figure L

Step 13. Push the plunger, at the top of the syringe, over at least 30 seconds until no SAJAZIR is in the syringe. See Figure M.

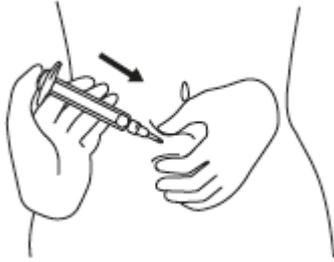


Figure M

Step 14. Release the skin fold and gently pull the needle out. See Figure N.

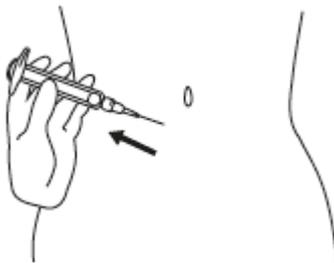


Figure N

Disposal of your used SAJAZIR prefilled syringe

Step 15. Place the used SAJAZIR syringe, with the needle attached, in a sharps container (such as a red biohazard container), a hard plastic container, (such as a detergent bottle), or a metal container (such as an empty coffee can). Seal the container and throw it away the right way. There may be state and local laws about the right way to throw away used syringes and needles. Ask your healthcare provider or pharmacist how to throw away used syringes and needles. See Figure O.



Figure O

This Patient Package Insert and Instructions for Use have been approved by the U.S. Food and Drug Administration.

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