



## Patient Information

### Icatibant (eye-KAT-i-bant) Injection

Please read this Patient Information before you use icatibant injection 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 icatibant injection?

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

#### What should I tell my healthcare provider before taking icatibant injection?

Before you use icatibant injection, tell your healthcare provider if you:

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

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

#### What should I avoid while using icatibant injection?

Tiredness, drowsiness, and dizziness can occur in people who take icatibant injection. 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 icatibant injection?

The most common side effects of icatibant injection 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 icatibant injection. 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 icatibant injection?

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

Keep icatibant injection and all medicines out of the reach of children.

#### General information about the safe and effective use of icatibant injection

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use icatibant injection for a condition for which it was not prescribed. Do not give icatibant injection 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 icatibant injection. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about icatibant injection that is written for health professionals.

#### What are the ingredients in icatibant injection?

**Active ingredient:** icatibant acetate

**Inactive Ingredients:** sodium chloride, glacial acetic acid, sodium hydroxide, and water

#### Step-by-Step Instructions for your icatibant injection

##### Step 1. Preparing your dose of icatibant injection

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

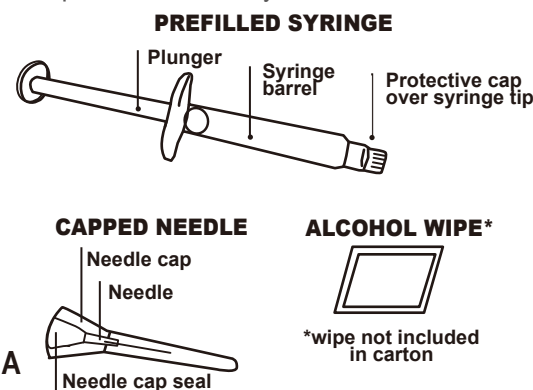


Figure A

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

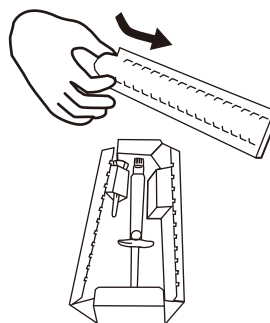


Figure B

##### 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 icatibant injection solution. See Figure D.

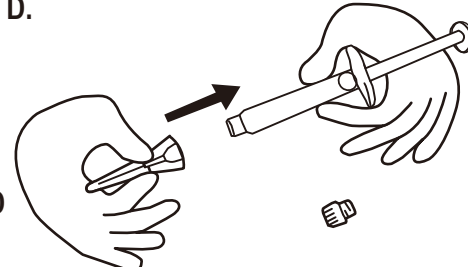


Figure D

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

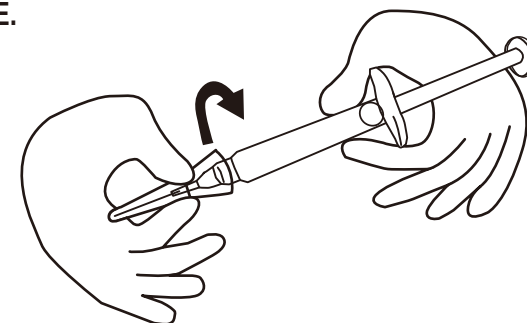


Figure E

#### 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.

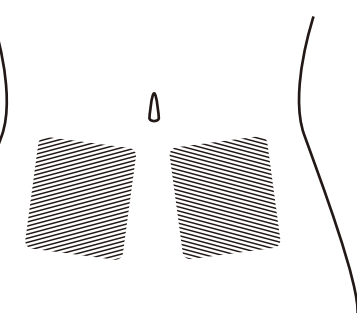


Figure F

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

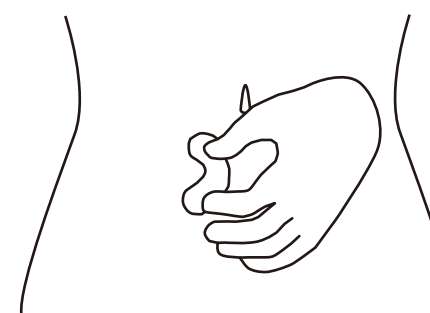


Figure G

#### Injecting your Icatibant Injection

##### 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.

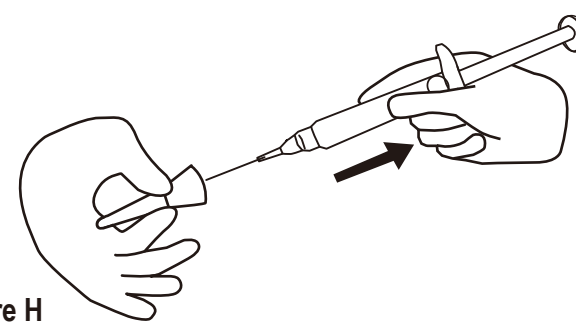


Figure H

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

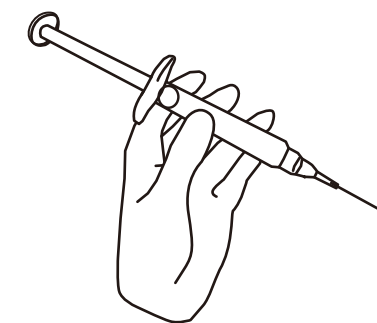


Figure I

##### 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.

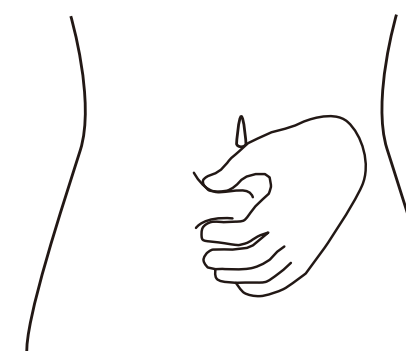


Figure J

##### 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.

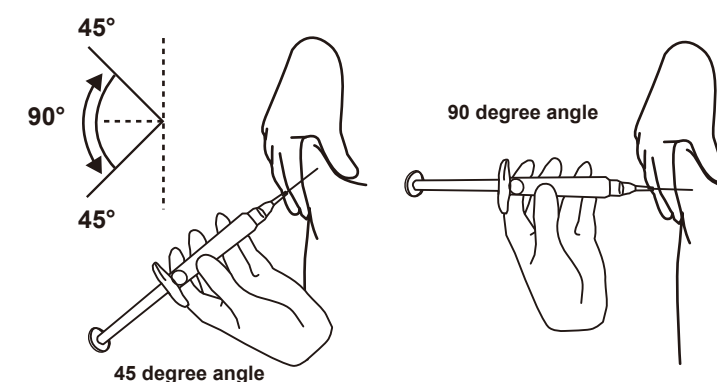


Figure K

##### 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.

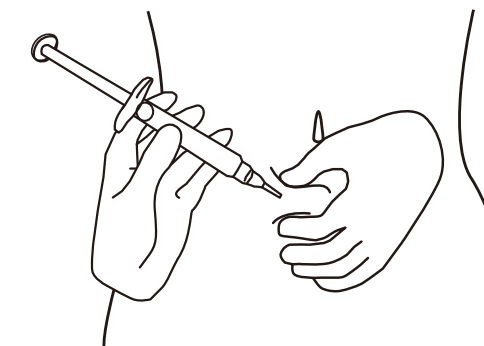


Figure L

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

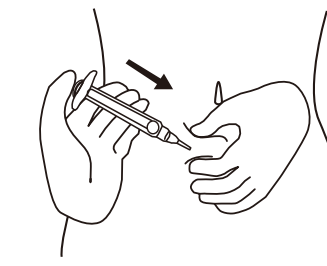


Figure M

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

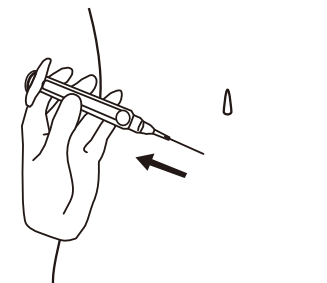


Figure N

#### Disposal of your used Icatibant Injection prefilled syringe

Step 15. Place the used icatibant injection 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.

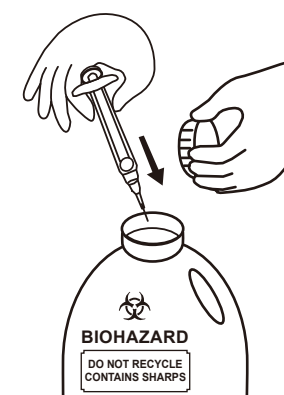


Figure O

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

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