

Icatibant Lupin

Active ingredient(s): icatibant acetate

Consumer Medicine Information (CMI)

This leaflet provides important information about using Icatibant Lupin. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Icatibant Lupin.**

Where to find information in this leaflet:

- [1. Why am I using Icatibant Lupin?](#)
- [2. What should I know before I use Icatibant Lupin?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Icatibant Lupin?](#)
- [5. What should I know while using Icatibant Lupin?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Icatibant Lupin?

Icatibant Lupin contains the active ingredient icatibant acetate. Icatibant Lupin is used for treating the symptoms of an acute attack of hereditary angioedema (HAE) in adults, adolescents and children aged 2 years and older.

During attacks of HAE, levels of a substance in your bloodstream called bradykinin are increased and this leads to symptoms like swelling, pain, nausea, and diarrhoea.

Icatibant Lupin blocks the activity of bradykinin and therefore, helps reduce the symptoms of an HAE attack.

2. What should I know before I use Icatibant Lupin?

Warnings

Do not use Icatibant Lupin if:

- you are allergic to icatibant acetate, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine. Some of the symptoms of an allergic response may include:
 - shortness of breath, wheezing or difficulty breathing;
 - swelling of the face, lips, tongue or other parts of the body, skin rash, itching or hives.

It is important to be able to tell when you might be having an allergic reaction as the symptoms are very similar to those of an attack of HAE, so you should discuss this with your doctor.

- the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering.
- there are any visible signs of deterioration (eg. if the solution is cloudy, if it has floating particles, or if the solution is not colourless).

Do not give Icatibant Lupin to a child under 2 years of age or weighing less than 12 kg.

If you are not sure whether you should use Icatibant Lupin, talk to your doctor.

Check with your doctor if you:

- have any other medical conditions such as:
 - you are suffering from angina (reduced blood flow to the heart muscle);
 - you have recently suffered a stroke.
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Icatibant Lupin may interact with medicines known as Angiotensin Converting Enzyme (ACE) inhibitors (eg. captopril, enalapril, ramipril, quinapril, lisinopril), which are used to lower your blood pressure or for any other reason.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Icatibant Lupin.

4. How do I use Icatibant Lupin?

Icatibant Lupin comes in a ready-to-use syringe. A needle is packed separately which you need to attach before use. Each syringe should only be used once. The medicine inside your Icatibant Lupin pre-filled syringe should be clear and colourless.

How much and how frequently to use Icatibant Lupin

- Follow the instructions provided and use Icatibant Lupin until your doctor tells you to stop.
- Your doctor will determine the exact dose of Icatibant Lupin and will tell you how often it should be used.

Adults:

- The recommended dose of Icatibant Lupin is one injection (30 mg in 3 mL) given subcutaneously (under the skin) as soon as you develop symptoms of an angioedema attack (eg. increased skin swelling, particularly affecting the face and neck, increasing tummy pain).
- If the HAE symptoms are still present, or return after initial relief, an additional injection of Icatibant Lupin (3 mL) may be given after 6 hours.
- If after a further 6 hours you still experience symptoms you may need a third injection of Icatibant Lupin (3 mL).
- **You should have no more than 3 injections in a 24-hour period and no more than 8 injections in a month.**

Children and adolescents aged 2 to 17 years:

- The recommended dose of Icatibant Lupin is one injection of 1 mL up to a maximum of 3 mL based on body weight given subcutaneously (under the skin) as soon as you develop symptoms of an angioedema attack.
- The dose will be determined by your doctor based on your child's body weight.
- The dose will increase over time as your child grows and the doctor will need to periodically review that the dose is appropriate.

The decision to initiate caregiver or self-administration of Icatibant Lupin should be made by a physician experienced in the diagnosis and treatment of HAE. Icatibant Lupin may be administered by a healthcare professional.

Please see step-by-step instructions for the dose to inject in children and adolescents.

If you are not sure which dose to inject, ask your doctor, pharmacist or nurse.

You must seek immediate medical help if your symptoms get worse or do not improve.

How to inject Icatibant Lupin

Icatibant Lupin is intended for subcutaneous injection (under the skin). Icatibant Lupin is injected into the fatty tissue under the skin in the abdomen (tummy).

Please see step-by-step instructions for injecting Icatibant Lupin at the end of this leaflet.

Adults:

- Icatibant Lupin injections are usually administered by healthcare professionals. If you wish to inject Icatibant Lupin yourself and the doctor agrees it is appropriate

(eg. if you have a lot of HAE attacks or if you live far from a hospital or doctor), you will be trained on how to give yourself an injection.

- **You or your caregiver must be trained on subcutaneous injection technique before you self-inject, or your caregiver injects you with Icatibant Lupin.**
- **Immediately after you self-inject Icatibant Lupin or your caregiver injects you with Icatibant Lupin while you are experiencing a laryngeal attack (obstruction of the upper airway), you must seek medical care in a medical institution.**

The following information is for patients who have been trained to inject themselves:

- As HAE attacks can often be serious, it is best to contact your doctor or hospital when you experience an attack.
- **If the HAE attack involves your face, lips, throat, or voice box, or if you have any difficulty breathing, you should always contact your doctor or hospital.**
- **If your HAE attack has not shown signs of improvement within 2 hours of the injection of Icatibant Lupin, or if the attack spreads to your face, lips, throat, or voice box, or you develop any difficulty breathing, you should contact your doctor or hospital immediately.**
- It is possible to have further injections of Icatibant Lupin if you do not have relief from the HAE symptoms following the first injection; however, this should be done by your doctor or in hospital (see below) or following the advice of your doctor.

Children and adolescents aged 2 to 17 years:

- Icatibant Lupin injections are usually administered by healthcare professionals, or by the caregiver of the child.
- **The caregiver must be trained on subcutaneous injection technique before administering Icatibant Lupin to the child.**
- **Immediately after administering Icatibant Lupin to the child while they are experiencing a laryngeal attack (obstruction of the upper airway), the child must seek medical care in a medical institution.**
- As HAE attacks can often be serious, it is best to contact your doctor or hospital when the child experiences an attack.
- If the HAE attack involves the face, lips, throat, or voice box, or if the child has any difficulty breathing, contact the doctor or hospital.
- If the HAE attack has not shown signs of improvement within 2 hours of the injection of Icatibant Lupin, or if the attack spreads to the face, lips, throat, or voice box, or the child develops any difficulty breathing, contact the doctor or hospital immediately.
- No more than one injection was given to a child for each HAE attack in clinical studies.

If you use too much Icatibant Lupin

If you think that you have used too much Icatibant Lupin, you may need urgent medical attention.

You should immediately:

- telephone the National Poisons Centre (telephone 0800 POISON or 0800 764 766);
- contact your doctor; or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

When high doses have been given, patients have experienced a drop in blood pressure.

5. What should I know while using Icatibant Lupin?

Things you should do

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Icatibant Lupin.

Call your doctor straight away if you:

- notice that your symptoms of the attack get worse after you use Icatibant Lupin. Some of the side effects connected with Icatibant Lupin are similar to the symptoms of your disease.
- become pregnant while using this medicine.

Remind any doctor, dentist or pharmacist you visit that you are using Icatibant Lupin.

Driving or using machines

Do not drive or operate any machinery if you feel tired or dizzy as a result of your HAE attack or after using Icatibant Lupin.

Be careful before you drive or use any machines or tools until you know how Icatibant Lupin affects you.

Looking after your medicine

- **Keep your medicine in the pack until it is time to use it.** If you take the medicine out of the pack it may not keep well.
- **Keep the medicine in a cool dry place where the temperature stays below 25°C. Do not freeze it.**

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink; or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Very common side effects:</p> <p>Almost all patients receiving Icatibant Lupin will experience a reaction at the site of the injection. These effects are usually mild and clear up by themselves without the need for any additional treatment.</p> <p>The reaction may include:</p> <ul style="list-style-type: none">• burning sensations;• reddening of the skin (erythema);• pain;• swelling;• feeling of warmth;• itching (pruritus). <p>More common side effects:</p> <p>Mostly, these are mild and short-lived. These are:</p> <ul style="list-style-type: none">• nausea;• pain in the abdomen (tummy);• weakness;• dizziness;• headache;• blocked nose;• rash;• vomiting;• fatigue;• fever;• sore throat;• weight gain;• asthma;• cough;• itching;• redness of the skin;• hot flushes;• muscle spasm;• hives;• abnormal liver function test (symptoms may include yellowing of the skin and eyes (jaundice)).	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to Medsafe online at <https://pophealth.my.site.com/carmreportnz/s/>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Icatibant Lupin contains

Active ingredient (main ingredient)	Icatibant acetate
Other ingredients (inactive ingredients)	Sodium chloride Glacial acetic acid Sodium hydroxide Water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What Icatibant Lupin looks like

Icatibant Lupin is supplied as a sterile solution for injection in single use pre-filled syringes. The solution should be clear and colourless and free from visible particles.

Sponsor Details

Lupin NZ Limited
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Level 4, Building A, BDO Centre
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Step-by-step instructions for injecting Icatibant Lupin

1. General Information

- Clean the work area (surface) to be used before beginning the process.
- Wash your hands with soap and water.
- Remove the pre-filled syringe from the tray.
- Remove the cap from the end of the pre-filled syringe by unscrewing the cap.
- Put down the pre-filled syringe after unscrewing the cap.

2a. Preparing the syringe for children and adolescents (2-17 years) weighing 65 kg or less

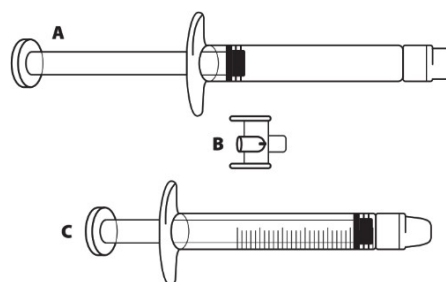
For patients who have not previously received Icatibant Lupin, initial treatment should be given in a medical institution or under the guidance of a physician. The decision to initiate caregiver or self-administration of Icatibant Lupin should only be made by a physician experienced in the diagnosis and treatment of HAE.

Icatibant Lupin may be administered by a caregiver only after training in subcutaneous injection technique by a healthcare professional.

Important information for healthcare professionals and caregivers

Where the dose is less than 30 mg (3 mL), the following equipment is required to extract the appropriate dose (see below):

- Icatibant Lupin pre-filled syringe (containing icatibant solution)
- Adapter (connector)
- 3 mL graduated syringe



The required injection volume in mL should be drawn up in an empty 3 mL graduated syringe (see table below).

Table 1: Dosage regimen for children and adolescents

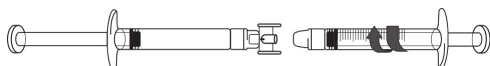
Body Weight	Injection Volume
12 kg to 25 kg	1.0 mL
26 kg to 40 kg	1.5 mL
41 kg to 50 kg	2.0 mL
51 kg to 65 kg	2.5 mL

Patients weighing more than 65 kg will use the full contents of the pre-filled syringe (3 mL).

If you are not sure which volume of solution to extract, ask your doctor, pharmacist or nurse.

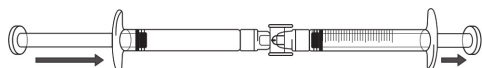
Preparing to extract dose less than 3 mL:

- Remove the caps on each end of the adapter.
Avoid touching the ends of the adapter and syringe tips, to prevent contamination.
- Screw the adapter onto the pre-filled syringe.
- Attach the graduated syringe to the other end of the adapter ensuring that both connections fit securely.

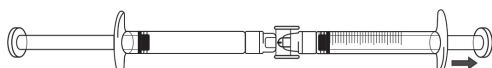


Transferring Icatibant Lupin solution to the graduated syringe:

- To start transfer of Icatibant Lupin solution, push the pre-filled syringe plunger (on far left of the below image).



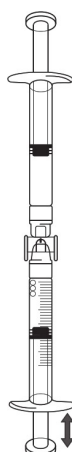
- If the Icatibant Lupin solution does not begin to transfer to the graduated syringe, pull slightly on the graduated syringe plunger until the Icatibant Lupin solution starts to flow into the graduated syringe (see below image).



- Continue to push on the pre-filled syringe plunger until the required injection volume (dose) is transferred to the graduated syringe. See **Table 1** for dosage information.

If there is air in the graduated syringe:

- Turn the connected syringes so that the pre-filled syringe is on top (see below image).



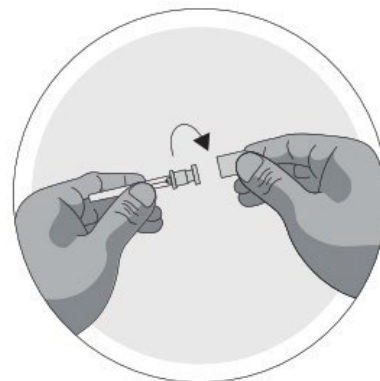
- Push the plunger of the graduated syringe so that any air is transferred back into the pre-filled syringe (this step may need to be repeated several times).
- Withdraw the required volume of Icatibant Lupin solution.

After transfer of Icatibant Lupin solution to the graduated syringe:

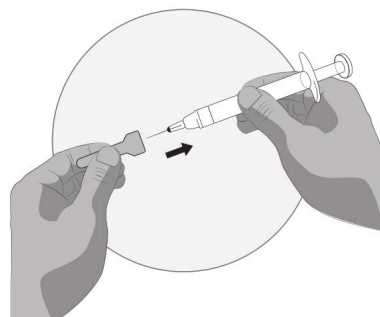
- Remove the pre-filled syringe and adapter from the graduated syringe.
- Discard the pre-filled syringe and adapter into the sharps container

2b. Preparing the syringe and needle for injection: All patients (adults, adolescents and children)

- Remove the needle cap from the blister tray.
- Twist the lid of the needle cap to break the seal (the needle should be still in the needle cap).

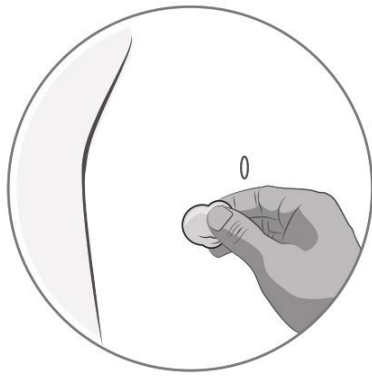


- Grip the syringe firmly. Carefully attach the needle to the syringe containing the colourless solution.
- Screw the syringe on the needle still fixed in the needle cap.
- Remove the needle from the needle cap by pulling the syringe. Do not pull up on the plunger.
- The syringe is now ready for injection.



3. Preparing the injection site

- Choose the injection site. The injection site should be a skin fold on your abdomen (tummy), approximately 5 to 10 cm below your navel (belly button) on either side. This area should be at least 5 cm away from any scars. Do not choose an area that is bruised, swollen, or painful.
- Clean the injection site with an alcohol wipe and allow it to dry

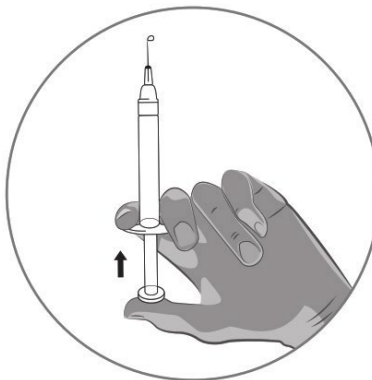


- Ask your pharmacist if you are not sure about the right way to throw away used syringes and needles.



4. Injecting the solution

- Hold the syringe in one hand between two fingers with your thumb at the bottom of the plunger.
- Make sure that there is no air bubble in the syringe by pressing the plunger until the first drop appears on the tip of the needle.



- Hold the syringe between a 45 to 90 degrees angle to your skin with the needle facing the skin.
- Keeping the syringe in one hand, use your other hand to gently hold a fold of skin between your thumb and fingers at the previously disinfected injection site.
- Hold the fold of the skin, bring the syringe to the skin and quickly insert the needle into the skin fold
- Slowly push the plunger of the syringe with a steady hand until all the solution is injected into the skin and no liquid remains in the syringe.
- Press slowly so that this takes approximately 30 seconds.
- Release the skin fold and gently pull the needle out.



5. Disposal of the injection material

- Discard the syringe, needle and needle cap into the sharps container.