



ICATIBANT

Patient Guide

ICATIBANT LUPIN

(Icatibant acetate solution for injection)

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About this Guide

This guide provides you with important information to support you while using Icatibant Lupin (icatibant acetate solution for injection).

This guide will help you to learn about:

- How Icatibant Lupin can be a key part of your hereditary angioedema (HAE) treatment plan.
- How to treat HAE attacks with Icatibant Lupin.
- Recognise potential side effects of Icatibant Lupin treatment.

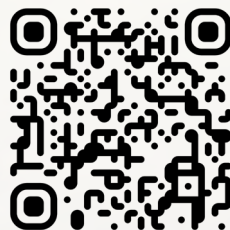
Please always read the Consumer Medicine Information (CMI), this instruction manual and pack insert, as applicable, supplied with your medicine in full before use.

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.

This guide is also available to download from **Lupin NZ** website:
<https://www.lupin.co.nz/products/icatibant-lupin/>

Scan the QR code below for Consumer Medicine Information or find it at
<https://www.medsafe.govt.nz/Consumers/CMI/I/IcatibantLupin.pdf>

Scan the QR code below for
Consumer Medicine Information



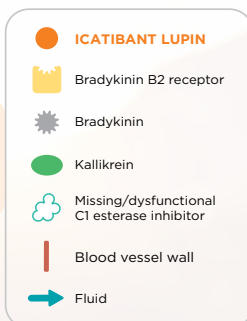
Icatibant Lupin in Patients with Hereditary Angioedema (HAE)

Icatibant Lupin contains the active ingredient icatibant acetate.

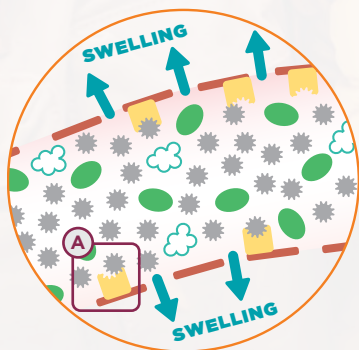
Icatibant Lupin is used for treating the symptoms of an acute attack of HAE in adults, adolescents and children aged 2 years or older.

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

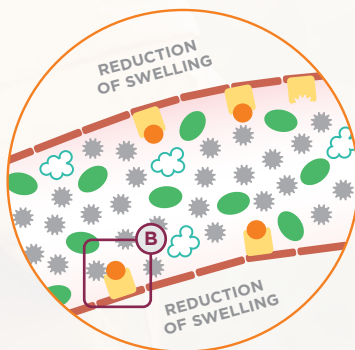


Untreated person with HAE during an attack



A Bradykinin binds to B2 receptors

Person with HAE after treatment with Icatibant Lupin



B Icatibant Lupin blocks bradykinin from binding to B2 receptors

Pack Details



Icatibant Lupin is supplied as pack of one single use pre-filled glass syringe and one needle.

The ready-to-use pre-filled syringe contains 30 mg icatibant (as acetate) in 3 mL sterile solution for injection.

A 25 gauge, 16 mm needle is included in the pack and needs to be attached to the syringe before use.

Each syringe must be used only once.

The solution inside the syringe must be clear and colourless and free from visible particles.

Important Safety Precautions

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).

Guide to Using Icatibant Lupin

The following instructions explain how to use Icatibant Lupin. Please read the instructions carefully and follow them step-by-step.

Adults may self-administer Icatibant Lupin after training under the guidance of a healthcare professional.

Icatibant Lupin may be administered to children and adolescents (2-17 years of age) by a caregiver, only after training in subcutaneous injection technique by a healthcare professional.

Seek urgent medical attention if there is no evidence of resolution of the HAE attack within 2 hours of self-injection, or immediately should the HAE attack progress to involve the face, lips or pharyngolaryngeal area.

Should the initial HAE attack involve the face, lips or pharyngolaryngeal area urgent medical attention should be sought.

Getting started

You will need the following supplies:

- Icatibant Lupin pack, which includes 1 single-use, pre-filled syringe and 1 needle.
- An alcohol swab (not included in the pack).

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.
- Unscrew the cap from the end of the pre-filled syringe.
- After unscrewing the cap, place the pre-filled syringe on the work area.

Do not proceed if

- **Expiry date printed on the pack has passed.**
- **Packaging is torn or shows signs of tampering.**
- **Solution is cloudy, has floating particles, or not colourless.**

A. Preparing the Syringe and Needle



1 Remove the needle cap from the blister tray.



2 Twist the lid of the needle cap to break the seal (the needle should be still in the needle cap).



3 Grip the syringe firmly. Carefully attach the needle to the syringe containing the colourless solution.

4 Screw the needle (still fixed in the needle cap) onto the syringe.

5 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.

B. Preparing the Injection Site



1

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.



2

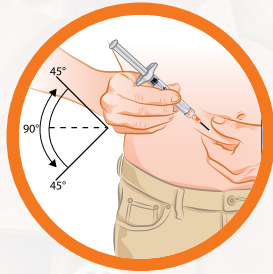
Clean the injection site with an alcohol wipe and allow it to dry.

C. Injecting Icatibant Lupin



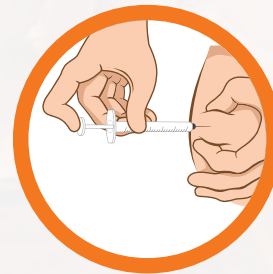
1 Hold the syringe in one hand between two fingers with your thumb at the bottom of the plunger.

2 Make sure that there are no air bubbles in the syringe by pressing the plunger until the first drop appears on the tip of the needle.



3 Hold the syringe between a 45 to 90 degree angle to your skin with the needle facing the skin.

4 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.



5 Hold the fold of the skin, bring the syringe to the skin and quickly insert the needle into the skin fold.

6 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.

7 Press slowly so that this takes approximately 30 seconds.

8 Release the skin fold and gently pull the needle out.

D. Disposal of Injection Material



- 1 Discard the syringe, needle and needle cap into the sharps container.
- 2 Ask your pharmacist if you are not sure about the right way to throw away used syringes and needles.

Dose Adjustment in Children and Adolescents



Icatibant Lupin must not be given in a child under 2 years of age or weighing less than 12 kg.



Patients please discuss the dose adjustments with your doctor or healthcare provider.
Pharmacists and Medical Practitioners should consult the Data Sheet.

Short-Form Consumer Medicine Information (CMI) Icatibant Lupin (icatibant acetate) Prescription medicine

What is Icatibant Lupin used for? Icatibant Lupin is used to treat acute attacks of hereditary angioedema (HAE) in adults, adolescents, and children aged 2 years and older with C1-esterase inhibitor deficiency. It works by blocking the effects of bradykinin, a substance that causes swelling and pain during an HAE attack.

Before you use Icatibant Lupin: Do not use this medicine if you: are allergic to icatibant or any of the ingredients; notice the solution is cloudy, contains particles, or the packaging is damaged; are under 2 years of age or weigh less than 12 kg.

Talk to your doctor before use if you: are pregnant or breastfeeding; have heart or liver problems; have frequent or severe HAE attacks; have any other medical conditions. Tell your doctor about all medicines you are taking.

How do I use Icatibant Lupin? Your doctor will tell you how much to use.

Typical doses: Adults: 30 mg injected under the skin as soon as symptoms begin.

Children (2-17 years): dose depends on body weight. If symptoms continue, additional doses may be given at least 6 hours apart. Do not use more than 3 doses in 24 hours or 8 doses in a month.

Icatibant Lupin is injected under the skin, usually in the abdomen. You may self-inject after being trained, or a healthcare professional may administer it. Seek emergency medical care immediately if your symptoms involve the throat, tongue, or voice box.

Possible side effects

Common side effects: redness, swelling, pain, or itching at the injection site; nausea; stomach pain; headache; dizziness; rash; tiredness; fever. **Serious side effects (seek urgent medical help):** difficulty breathing; swelling of the face, lips, or throat; severe dizziness.

How do I store Icatibant Lupin? Store below 25°C. Do not freeze. Keep in original packaging to protect from light. Keep out of reach of children.

What else do I need to know? Icatibant Lupin is a prescription medicine. Use only as directed and consult your healthcare professional if symptoms persist. For more information, contact your doctor or pharmacist, or Lupin NZ Ltd at the details below.

Sponsor: Lupin NZ Ltd, Level 4, Building A, BDO Centre 4 Graham Street, Auckland Central Auckland 1010, New Zealand. Additional product information and Consumer Medicine Information (CMI) can be found at Medsafe.govt.nz or by phoning 0800 600 597.