▼ **This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.**

Cipla Icatibant

(Icatibant acetate)

Consumer Medicine Information

What is in this leaflet

Please read this leaflet before you start using Cipla Icatibant.
This leaflet answers some common questions about Cipla Icatibant. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Cipla Icatibant against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor, nurse or pharmacist.

Keep this leaflet with the medicine.
You may need to read it again.

What Cipla Icatibant is used for

Cipla Icatibant 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.

How it works

Cipla Icatibant contains the active ingredient icatibant. It blocks the activity of bradykinin and therefore, helps reduce the symptoms of an HAE attack.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine is not addictive.

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

Before you use Cipla Icatibant

When you must not use it

Do not use Cipla Icatibant if you have an allergy (hypersensitivity) to icatibant, or any of the other ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction 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.

Do not give Cipla Icatibant to a child under 2 years of age or weighing less than 12 kg.
Cipla Icatibant is not registered for use in children under 2 years of age or weighing less than 12 kg.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.
If it has expired or is damaged, return it to your pharmacist for disposal.

Do not use Cipla Icatibant if there are any visible signs of deterioration, for example if the solution is cloudy, if it has floating particles, or if the solution is not colourless.

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

Before you start to use it

Consult your doctor before using Cipla Icatibant if:

- **you are suffering from angina (reduced blood flow to the heart muscle)**
- **you have recently suffered a stroke**

Tell your doctor before using Cipla Icatibant if you are taking a medicine known as an Angiotensin Converting Enzyme (ACE) inhibitor (for example: captopril, enalapril, ramipril, quinapril, lisinopril) which is used to lower your blood pressure or for any other reason.

Tell your doctor if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

If you are pregnant or plan on becoming pregnant, discuss this with your doctor before using Cipla Icatibant.
Your doctor will discuss the possible risks and benefits of using Cipla Icatibant during pregnancy.

Tell your doctor if you are breastfeeding. You should not breastfeed for 12 hours after you have used Cipla Icatibant.
It is not known whether icatibant passes into your breast milk.

Cipla Icatibant contains Sodium

The injection solution contains less than 1 mmol (23 milligrams) of sodium, so it is essentially 'sodium-free'.

Taking other medicines

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

Cipla Icatibant can interact with other medicines, e.g. ACE inhibitors (as previously discussed).

Food and drink have no effect on the action of Cipla Icatibant.

How to use Cipla Icatibant

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

Cipla Icatibant 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 Cipla Icatibant pre-filled syringe should be clear and colourless. Do not use your Cipla Icatibant if the solution contains particles, is cloudy, or has an unusual colour.

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

Adults:

Cipla Icatibant injections are usually administered by healthcare professionals. If you wish to inject Cipla Icatibant yourself and the doctor agrees it is appropriate (e.g. 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 Cipla Icatibant.

Immediately after you selfinject Cipla Icatibant or your caregiver injects you with Cipla Icatibant 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 Cipla Icatibant; 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 Cipla Icatibant 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:

Cipla Icatibant 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 Cipla Icatibant to the child. Immediately after administering Cipla Icatibant to the child while he/she is 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 Cipla Icatibant; 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.

How much and when it is given

Your doctor will determine the exact dose of Cipla Icatibant and will tell you how often it should be used.

Adults:

The recommended dose of Cipla Icatibant is one injection (30 mg in 3 mL) given subcutaneously (under the skin) as soon as you develop symptoms of an angioedema attack (e.g. 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 Cipla Icatibant (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 Cipla Icatibant (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 Cipla Icatibant 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 (e.g. increased skin swelling, particularly affecting the face and neck, increasing tummy pain).

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 should be made by a physician experienced in the diagnosis and treatment of HAE. Cipla Icatibant 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.

If you use too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (Australia: 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital if you think that you or anyone else may have used too much Cipla Icatibant. 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.

While you are using Cipla Icatibant

Things you must do

Tell your doctor immediately if you notice that your symptoms of the attack get worse after you use Cipla Icatibant.

Some of the side effects connected with Cipla Icatibant are similar to the symptoms of your disease.

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

Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine.

If you become pregnant while using this medicine, tell your doctor immediately.

Things to be careful of

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Cipla Icatibant.

Like all medicines, Cipla Icatibant can cause some side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Almost all patients receiving Cipla Icatibant will experience a reaction at the site of the injection. The reaction may include burning sensations, reddening of the skin (erythema), pain, swelling, feeling of warmth, and itching (pruritus). These effects are usually mild and clear up by themselves without the need for any additional treatment.

Tell your doctor or pharmacist if you notice any of the following symptoms and they worry you:

- 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)).

These are the more common side effects of Cipla Icatibant. Mostly, these are mild and short-lived.

Tell your doctor, nurse or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly at http://www.tga.gov.au/reporting-problems. By reporting side effects you can help provide more information on the safety of this medicine.

After using Cipla Icatibant

Storage

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.

Do not store Cipla Icatibant or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.
Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.
A locked cupboard at least one-anda-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What Cipla Icatibant looks like

Cipla Icatibant is supplied as 30 mg icatibant (as acetate) in 3 mL in one single use pre-filled glass syringe (type I) with bromobutyl plunger stopper. The solution is clear and colourless and free from visible particles. A hypodermic needle (25 G; 16 mm) is included in the package.

Ingredients

Active ingredient:

Icatibant acetate (equivalent to 30 mg of icatibant) in 3 mL solution for injection in each pre-filled syringe.

Other ingredients:

- sodium chloride
- glacial acetic acid
- sodium hydroxide
- water for injections.

Cipla Icatibant does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

Cipla Australia Pty Ltd
Level 1, 132-136 Albert Road
South Melbourne Vic 3205

Date of Preparation

This leaflet was prepared in April, 2020.

Australian Registration Number:

AUST R 314007

Step-by-step instructions for injecting Cipla Icatibant

1. General information

- Clean the work area (surface) to be used before beginning the process.
- Wash your hands with soap and water
- Open the blister tray by peeling back the seal.
- Remove the pre-filled syringe from the blister 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 Cipla Icatibant, 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 Cipla Icatibant should only be made by a physician experienced in the diagnosis and treatment of HAE.

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

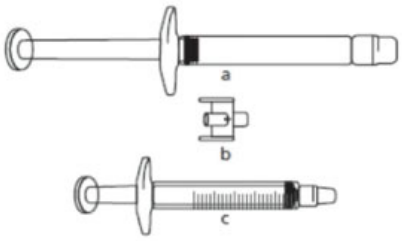
Important information for healthcare professionals and caregivers:

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

a) Cipla Icatibant pre-filled syringe (containing icatibant solution)

b) Adapter (connector)

c) 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:

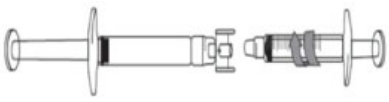
Body weight	Injection volume
12 kg to 25 kg	1.0 mL
26 kg to 40 kg	1.5 mL
41 kg to 50 kg	2.0 mL
51 kg to 65 kg	2.5 mL

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

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

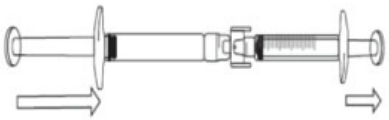
Preparing to extract dose less than 3 mL:

- 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 prefilled syringe.
- Attach the graduated syringe to the other end of the adapter ensuring that both connections fit securely.

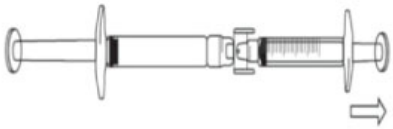


Transferring Cipla Icatibant solution to the graduated syringe:

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



- If the Cipla Icatibant solution does not begin to transfer to the graduated syringe, pull slightly on the graduated syringe plunger until the Cipla Icatibant 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).

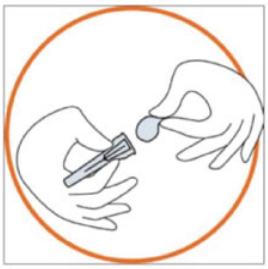
- Push the plunger of the graduated syringe so that any air is transferred back into the prefilled syringe (this step may need to be repeated several times).
- Withdraw the required volume of Cipla Icatibant solution.

After transfer of Cipla Icatibant solution to the graduated syringe:

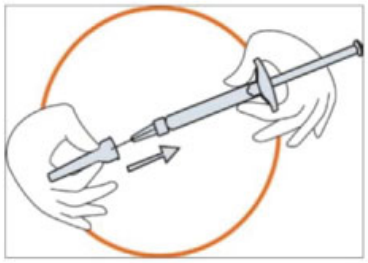
- Remove the pre-filled syringe and adapter from the graduated syringe.
- Discard the pre-filled syringe and adapter into the sharps container.

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

- Remove the needle cap from the blister tray.
- Remove the seal from the needle cap (the needle should be still in the needle cap)

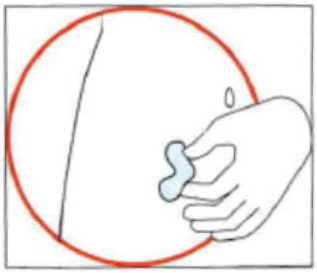


- Grip the syringe firmly. Carefully attach the needle to the syringe containing the colourless solution.
- Screw the syringe on the needle still fixed in the needle cap.
- Remove the needle from the needle cap by pulling the syringe. Do not pull up on the plunger.
- The syringe is now ready for injection.



3. Preparing the Injection Site

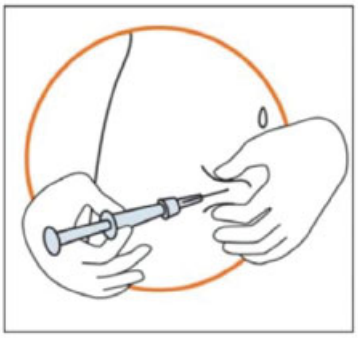
- Choose the injection site. The injection site should be a skin fold on your abdomen (tummy), approximately 5 to 10 cm below your navel (belly button) on either side. This area should be at least 5 cm away from any scars. Do not choose an area that is bruised, swollen, or painful.
- Clean your injection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



4. Injecting the solution

- Hold the syringe in one hand between two fingers and 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 degree angle to your skin with the needle facing the fold of 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.
  Ask your pharmacist if you are not sure about the right way to throw away used syringes and needles.