

Icanticure Injection 30mg / 3mL in Prefilled Syringe

Icatibant Acetate (eq. to Icatibant) 30 mg / 3mL

What is in this leaflet

1. What Icanticure is used for
2. How Icanticure works
3. Before you use Icanticure
4. How to use Icanticure
5. While you are using it
6. Side effects
7. Storage and Disposal of Icanticure
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial number

What Icanticure is used for

Icanticure contains the active substance icatibant.

Icanticure is used for treating the symptoms of hereditary angioedema (HAE) in adults, adolescents and children aged 2 years and older.

How Icanticure works

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

Icanticure blocks the activity of bradykinin and therefore ends the further progression of the symptoms.

Before you use Icanticure

-When you must not use it

- If you are allergic to icatibant, or any of the other ingredients of this medicine listed in section 'Ingredients'
- If you are pregnant or may become pregnant

-Before you start use

Talk to your doctor before taking Icanticure:

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

Some of the side effects connected with Icanticure are similar to the symptoms of your disease. Tell your doctor immediately if you notice that your symptoms of the attack get worse after you received Icanticure.

In addition:

- You or your caregiver must be trained on subcutaneous (under the skin) injection technique before you self-inject or your caregiver injects you with Icanticure.
- Immediately after you self-inject Icanticure or your caregiver injects you with Icanticure while you are experiencing a laryngeal attack (obstruction of the upper airway), you must seek medical care in a medical institution.
- If your symptoms are not resolved following one self- or caregiver administered injection of Icanticure, you should seek medical advice regarding additional injections of Icanticure. For adult patients, up to 2 additional injections may be given within 24 hours.

Children and adolescents

Icanticure is not recommended for use in children under 2 years of age or weighing less than 12 kg because it has not been studied in these patients.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor before starting to use Icanticure.

If you are breast-feeding you should not breast-feed for 12 hours after you have last received Icanticure.

-Taking other medicines

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

Icanticure is not known to interact with other medicines. 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, you should inform your doctor before receiving Icanticure.

How to use Icanticure

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

If you have never received Icanticure previously, your first dose of Icanticure will always be injected by your doctor or nurse. Your doctor will tell you when it is safe for you to go home. After discussion with your doctor or nurse and after training in subcutaneous (under the skin) injection technique, you may be able to inject yourself with Icanticure or your caregiver may inject Icanticure for you when you have an HAE attack. It is important that Icanticure is injected subcutaneously (under the skin) as soon as you notice an attack of angioedema. Your healthcare provider will teach you and your caregiver how to safely inject Icanticure by following the instructions in the Package Leaflet.

-How much to use

Your doctor has determined the exact dose of Icanticure and will tell you how often it should be used.

Adults

- The recommended dose of Icanticure is one injection (3 ml, 30 mg) injected subcutaneously (under the skin) as soon as you notice the attack of angioedema (for example increased skin swelling, particularly affecting the face and neck, or increasing tummy pain).
- If you experience no relief of symptoms after 6 hours, you should seek medical advice regarding additional injections of Icanticure. For adults, up to 2 additional injections may be given within 24 hours.
- **You should not have more than 3 injections in a 24 hour period and if you require more than 8 injections in a month, you should seek medical advice.**

Children and adolescents aged 2 to 17 years

- The recommended dose of Icanticure is one injection of 1 ml up to a maximum of 3 ml based on body weight injected subcutaneously (under the skin) as soon as you develop symptoms of

Icanticure Injection 30mg / 3mL in Prefilled Syringe

Icatibant Acetate (eq. to Icatibant) 30 mg / 3mL

an angioedema attack (for example increased skin swelling, particularly affecting the face and neck, increasing tummy pain).

- See section on instructions for use for the dose to inject.
- If you are not sure which dose to inject, ask your doctor, pharmacist or nurse.
- **If your symptoms get worse or do not improve, you must seek immediate medical help.**

-When to use it

Use as directed by your doctor or pharmacist.

-How long to use it

Adults

- You should not have more than 3 injections in a 24 hour period and if you require more than 8 injections in a month, you should seek medical advice.

Children and adolescents aged 2 to 17 years

- One injection of 1 ml up to a maximum of 3 ml based on body weight injected subcutaneously (under the skin) as soon as you develop symptoms of an angioedema attack.
- If your symptoms get worse or do not improve, you must seek immediate medical help.

While you are using Icanticure

-Things you must do

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using Icanticure.

Tell your doctor immediately if you become pregnant while using this medication.

Take Icanticure only with a doctor's prescription.

-Things you must not do

Do not stop using the medicine unless advised by your doctor.

Do not use any new medicines without consulting your doctor or pharmacist.

Do not give Icanticure to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

Driving and using machines

Do not drive or use machines if you feel tired or dizzy as a result of HAE attack or after using Icanticure.

Side Effects

Like all medicines, Icanticure can cause side effects, although not everybody gets them.

Almost all patients receiving Icanticure will experience a reaction at the site of the injection (such as skin irritation, swelling, pain, itchiness, redness of the skin and burning sensation). These effects are usually mild and clear up without the need for any additional treatment.

Very common (may affect more than 1 in 10 people):

Additional injection site reactions (pressure sensation, bruising, reduced sensation and/or numbness, raised itchy skin rash and warmth).

Common (may affect up to 1 in 10 people):

- Feeling sick
- Headache
- Dizziness
- Fever
- Itching
- Rash
- Skin redness
- Abnormal liver function test

Not known (frequency cannot be estimated from the available data):

- Hives (urticaria)

Tell your doctor immediately if you notice that the symptoms of your attack get worse after you received Icanticure.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Icanticure

-Storage

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date stated on the label after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 25°C. Do not freeze.

Do not use this medicine if you notice that the syringe or needle packaging is damaged or if there are any visible signs of deterioration, for example if the solution is cloudy, if it has floating particles, or if the colour of the solution has changed.

-Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

-What it looks like

Icanticure Injection 30mg/3ml in Prefilled syringe is supplied as a single-dose, prefilled syringe for subcutaneous administration. Each syringe delivers 3 mL of a clear and colorless sterile solution of icatibant 30 mg.

-Ingredients

Active ingredient(s)

Each pre-filled syringe of 3mL contains Icatibant acetate equivalent to 30mg Icatibant.

Inactive ingredients

Sodium chloride, glacial acetic acid, sodium hydroxide, and water for injection.

Icanticure Injection 30mg / 3mL in Prefilled Syringe

Icatibant Acetate (eq. to Icatibant) 30 mg / 3mL

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

-MAL number
MALXXXXX

Product Registration Holder

Nang Kuang Pharm Sdn. Bhd.
A-07-03A Ekocheras,
No. 693, Batu 5, Jalan Cheras, 56000
Kuala Lumpur.

Manufacturer

Nang Kuang Pharmaceutical Co., Ltd.
No.1001, 1001-1, Zhongshan Rd.,
Xinhua Dist., Tainan City, Taiwan
(R.O.C.).

Date of revision

30/6/2026

Serial Number

NPRA (R1) 26/016

Icanticure Injection 30mg / 3mL in Prefilled Syringe

Icatibant Acetate (eq. to Icatibant) 30 mg / 3mL

Instruction For Use

Icanticure is intended for subcutaneous injection (under the skin). Each syringe should only be used once.

Icanticure is injected with a short needle into the fatty tissue under the skin in the abdomen (tummy).

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Step-by-Step Instructions for your Icanticure

1) General Information

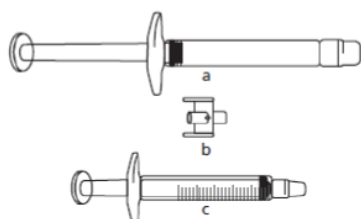
- Clean the work area (surface) to be used before beginning the process.
- Wash your hands with soap and water.
- Open the tray by peeling back the seal.
- Remove the pre-filled syringe from the tray.
- Remove the cap from the end of the pre-filled syringe by unscrewing the cap.
- Put down the pre-filled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

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

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):

- Icanticure pre-filled syringe (containing icatibant solution)
- Connector (adapter)
- 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 paediatric patients

Body Weight	Injection Volume
12 kg to 25kg	10 mg (1.0ml)
26 kg to 40 kg	15 mg (1.5ml)
41 kg to 50 kg	20 mg (2.0ml)
51 kg to 65 kg	25mg (2.5ml)
>65 kg	30 mg (3.0ml)

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

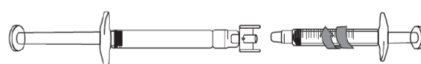
If you are not sure which volume of solution to extract, ask your doctor, pharmacist or nurse

- 1) Remove the caps on each end of the connector.

Avoid touching the ends of the connector and syringe tips, to prevent contamination

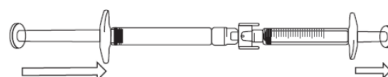
- 2) Screw the connector onto the pre-filled syringe.

- 3) Attach the graduated syringe to the other end of the connector ensuring that both connections fit securely.

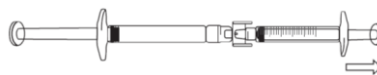


Transferring the icatibant solution to the graduated syringe:

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



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

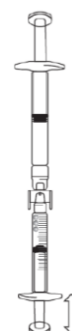


- 3) Continue to push on the pre-filled syringe plunger until the required

injection volume (dose) is transferred to the graduated syringe. Refer to 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 solution.

- 4) Remove the pre-filled syringe and connector from the graduated syringe.

- 5) Discard the pre-filled syringe and connector 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.

Icanticure Injection 30mg / 3mL in Prefilled Syringe

Icatibant Acetate (eq. to Icatibant) 30 mg / 3mL

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



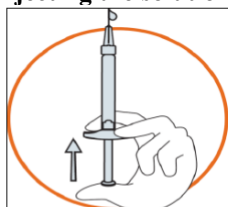
- Grip the syringe firmly. Carefully attach the needle to the syringe containing the colourless solution.
- Screw the syringe on the needle still fixed in the needle cap.
- Remove the needle from the needle cap by pulling the syringe. Do not pull up on the plunger.
- The syringe is now ready for injection.

3) Preparing the injection site



- Choose the injection site. The injection site should be a skin fold on your abdomen approximately 5-10 cm (2-4 inches) below your navel on either side. This area should be at least 5 cm (2 inches) away from any scars. Do not choose an area that is bruised, swollen, or painful.
- Clean the injection site with a rubbing alcohol pad and allow it to dry.

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 syringe between 45-90 degrees angle to skin with 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 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 fluid 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 sharp container for throwing away waste that might hurt others if not handled properly.