PATIENT INFORMATION LEAFLET

BRADİKANT 30 mg/3 ml Solution for S.C. Injection in Pre-Filled Syringe

For subcutaneous injection.

Sterile

- ***Active substance:*** Each pre-filled syringe containing 3 ml solution contains icatibant acetate equivalent to 30 mg of icatibant. Each ml of solution contains 10 mg of icatibant.
- ***Excipients:*** Sodium chloride, glacial acetic acid (for pH adjustment), sodium hydroxide (for pH adjustment), water for injection.

▼ 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. See the end of section 4 for how to report side effects.

Read all of this PATIENT INFORMATION LEAFLET carefully before you start using this medicine because it contains important information for you.

- *Keep this **PATIENT INFORMATION LEAFLET.** You may need to read it again.*
- *If you have any additional questions, please contact your physician or pharmacist.*
- *This medicine has been prescribed personally for you. Do not pass it on to others.*
- *When you go to doctor or hospital while using this medicine, tell your doctor that you are using this medicine.*
- *Please completely follow the instructions in this information leaflet. Do not use **higher** or **lower** doses other than what is recommended to you.*

In this leaflet:

1. ***What BRADİKANT is and what it is used for***
2. ***What you need to know before you use BRADİKANT***
3. ***How to use BRADİKANT***
4. ***Possible side effects***
5. ***How to store BRADİKANT***

headlines are included.

1. What BRADİKANT is and what it is used for

BRADİKANT contains the active substance icatibant.

BRADİKANT is presented as pre-filled syringe containing 3 ml of clear, colorless solution to be injected subcutaneously.

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

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

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

2. What you need to know before you use BRADİKANT

Do not use BRADİKANT

- If you are allergic to icatibant, or any of the other ingredients of this medicine.

Warnings and precautions

Talk to your doctor before taking BRADİKANT:
- 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 BRADİKANT 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 BRADİKANT

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 BRADİKANT.

- Immediately after you self-inject BRADİKANT or your caregiver injects you with BRADİKANT 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 BRADİKANT, you should seek medical advice regarding additional injections of BRADİKANT. For adult patients, up to 2 additional injections may be given within 24 hours.

Please consult your doctor if these warnings are valid for you, even at any time in the past.

Use with food and beverages

No data available.

Pregnancy

Before using this medicine consult your doctor or pharmacist.

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 BRADİKANT.

If you notice that you have been pregnant during treatment, consult immediately your doctor or pharmacist.

Breast-feeding

Before using this medicine consult your doctor or pharmacist.

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

Driving and using machines

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

BRADİKANT contains a small amount of sodium

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

Other medicines and BRADİKANT

Tell your doctor if you are taking, have recently taken or might take any other medicines.
BRADİKANT 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 BRADİKANT.

If you are taking or have recently taken any other medicines, including medicines without a prescription, tell your doctor or pharmacist.

3. How to use BRADİKANT

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 BRADİKANT previously, your first dose of BRADİKANT 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 BRADİKANT or your caregiver may inject BRADİKANT for you when you have an HAE attack. It is important that BRADİKANT 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 BRADİKANT by following the instructions in the Package Leaflet.

When and how often should you use BRADİKANT?

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

Adults:
The recommended dose of BRADİKANT 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 BRADİKANT. 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 BRADİKANT 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 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.

Administration route and method:

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

BRADİKANT 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.

The following step-by step instructions are intended for:
- Self-administration (adults)
- Administration by a caregiver or healthcare professional to adults, adolescents or children aged over 2 years (weighing at least 12 kg).

The instructions include the following main steps:

1) General Information
2) Preparing the injection site
2a) Preparing the syringe for children and adolescents (2-17 years) weighing 65 kg or less
2b) Preparing the syringe and needle for injection (all patients)
3) Injecting the solution
4) Disposal of the injection material

Step-by-Step Instructions for Injection

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.

2) 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.

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

Important information for health care professionals and care givers
Where the dose is less than 30 mg (3 ml), the following equipment is required to extract the appropriate dose (see below).

Dosage regimen for children and adolescents:

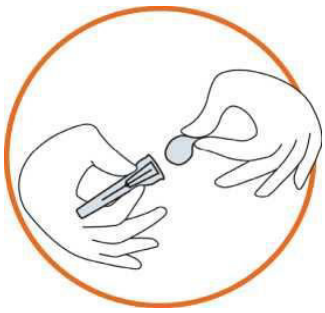
Body Weight	Dose (Injection Volume)
12 kg to 25 kg	10 mg (1.0 ml)
26 kg to 40 kg	15 mg (1.5 ml)
41 kg to 50 kg	20 mg (2.0 ml)

51 kg to 65 kg	25 mg (2.5 ml)
>65 kg	30 mg (3 ml)

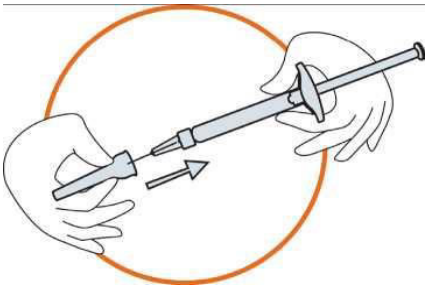
Patients weighing more than 65 kg will use the full contents of the pre-filled syringe (3 ml).

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

2b. Preparing the syringe and needle for injection

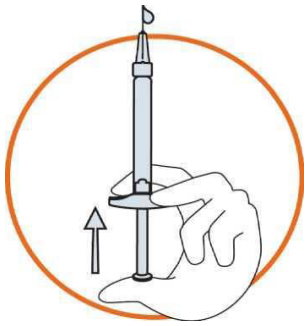


- Remove the needle cap from the blister.
- Remove the seal from the needle cap (the needle should be still in the needle cap).



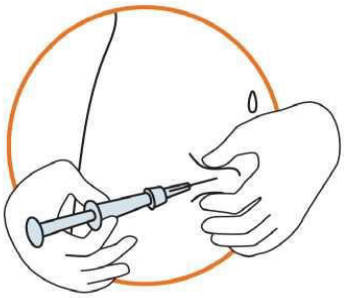
- Grip the syringe firmly. Carefully attach the needle to the syringe containing the colourless solution.
- Screw the syringe on the needle still fixed in the needle cap.
- Remove the needle from the needle cap by pulling the syringe. Do not pull up on the plunger.
- The syringe is now ready for injection.

3) 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.

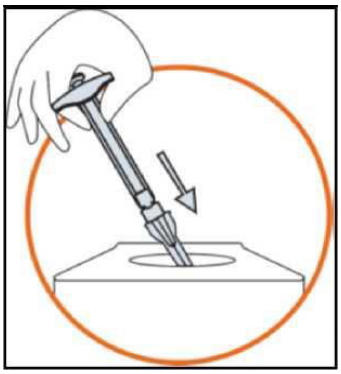
- Hold the fold of skin, bring the syringe to the skin and quickly insert the needle into the skin fold.

- 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.

4) 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.

Different age groups:
Use in children and adolescents:
BRADİKANT 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.

In the treatment of multiple Hereditary angioedema attacks with icatibant in pediatric patients There is limited experience.

Use in elderly:
There is limited information on its use in patients over 65 years of age. In elderly patients increased systemic exposure to icatibant has been shown. Safety of BRADİKANT is unknown for this case.

Special conditions for use:

Renal/Hepatic failure
No special use.

If you have the impression that the effect of BRADİKANT 1% is too strong or weak, Added with your doctor or pharmacist.

If you use more BRADİKANT than you should:
No clinical information is available regarding overdose. 3.2 mg/kg intravenously in healthy individuals (intravenous administration) dose (about 8 times the therapeutic dose) temporary redness, itching, neck and caused flushing or decreased blood pressure on the face. However, treatment was not required.

If you receive more BRADİKANT 1% than you should, tell your doctor or pharmacist.

If you forget using BRADİKANT
Do not take double dose to make up the dose you forgot.
Effects which may occur after terminate the treatment with BRADİKANT:
The dosage of BRADIKANT, the injection intervals and the duration of treatment should be carefully
It is a drug that must be determined. Effects that may occur after your treatment is completed
Consult your doctor about.

4. Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.

Almost all patients receiving BRADİKANT 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.

Side effects are listed as defined by following categories:

Very common : may be seen in at least one of 10 patients;
Common : may be seen in less than one of 10 patients but more than one of 100 patients;
Uncommon : may be seen in less than one of 100 patients but more than one of 1.000 patients;
Rare : may be seen less than 1 in 1,000 patients, but more than 1 in 10,000 patients.
Very rare : may be seen in at least one of 10.000 patients;
Unknown : cannot be estimated from the available data.

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

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

Unknown:
Hives (urticaria)

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

received BRADİKANT.

If you get any side effects talk to your doctor. This includes any possible side effects not listed in this leaflet.

5. How to store BRADİKANT

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

Do not use this medicine after the expiry date.

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 color of the solution has changed.

Do not throw away any medicines via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

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