

PACKAGE LEAFLET: INFORMATION FOR THE USER

{INVENTED NAME} 30 mg solution for injection, pre-filled syringe

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Icatibant

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Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What {Invented name} is and what it is used for
2. Before you use {Invented name}
3. How to use {Invented name}
4. Possible side effects
5. How to store {Invented name}
6. Further information

Comment [piq-qrd1]: Not part of the QRD template.

Deleted: This medicine will be administered by your doctor or nurse. ¶
- This medicine is not for self-administration

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1. WHAT {INVENTED NAME} IS AND WHAT IT IS USED FOR

{Invented name} is used for treating the symptoms of hereditary angioedema (HAE) in adult patients. In HAE levels of a substance in your bloodstream called bradykinin are increased and this leads to symptoms like swelling, pain, nausea, and diarrhoea.

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{Invented name} blocks the activity of bradykinin and therefore ends the further progression of the symptoms of an HAE attack.

2. BEFORE YOU USE {INVENTED NAME}

Do not use {Invented name}

- If you know that you are allergic (hypersensitive) to icatibant, or any of the other ingredients of {Invented name}.

Take special care with {Invented name}

- If you are suffering from myocardial ischemia (reduced blood flow to the heart muscle), please consult your doctor before using {Invented name}.

Comment [piq-qrd2]: This section should reflect info from 4.4 of the SPC. Stroke warning should be added here.

Using other medicines

{Invented name} is not known to interact with other medicines, but please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed by a doctor. If you take ACE inhibitors to lower your blood pressure or for any other reason, you should inform your doctor before receiving {Invented name}.

Comment [piq-qrd3]: Give some examples. How would a patient know what are ACE inhibitors? Moreover, explain the abbreviation.

Taking {Invented name} with food and drink

Food and drink have no effect on the action of {Invented name}.

Pregnancy and breast feeding

If you are pregnant or plan becoming pregnant, discuss this with your doctor before starting to use {Invented name}.

If you are breast-feeding you should not breast-feed for 12 hours after you have received {Invented name}.

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Driving and using machines

Do not drive or use machinery if you feel drowsy, tired or confused after having received {Invented name}.

Comment [piq-qrd4]: Not in line with SPC section 4.7!

Important information about some of the ingredients of {Invented name}

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

3. HOW TO USE {INVENTED NAME}

{Invented name} will always be injected by your doctor or nurse.
Your doctor will tell you when it is safe for you to go home.

When and how often should you use {Invented name}?

Your doctor has determined the exact dose of {Invented name} and will tell you how often it should be used. The recommended dose of {Invented name} is one syringe (3 ml, 30 mg) applied subcutaneously (under the skin) as soon as you notice the attack of hereditary angioedema becoming moderate or severe. If you experience no relief of symptoms after 6 hours, an additional injection of {Invented name} (3 ml) can be given. If after a further 6 hours you still experience no relief you might have a third injection {Invented name} (3 ml).

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Comment [piq-qrd5]: How will they know if it is becoming moderate or severe??

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You should not have more than 3 injections in a 24 hour period and no more than 8 injections of {Invented name} in total per month.

How should {Invented name} be administered?

{Invented name} is intended for subcutaneous injection (under the skin).

{Invented name} is injected with a short needle into the fatty tissue under the skin in the abdomen (tummy).

Comment [piq-qrd6]: Section on missed dose is missing as well as if you stop. Check QRD template.

4. POSSIBLE SIDE EFFECTS

Like all medicines, {Invented name} can cause side effects, although not everybody gets them. You will most likely get reactions at the injection site like 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.

Comment [piq-qrd7]: Specify frequency as below.

Comment [piq-qrd8]: Since those are symptoms similar to the HAE condition, it should be explained that they also could be side effects. This could preferably be explained also in another section. The patient might otherwise think that the medicine doesn't work

Very common (affects 1 to 10 users in 10 patients treated):

Injection site reactions (burning sensations, reddening of the skin, pain, swelling, feeling of warmth, itching.)

Common (affects 1 to 10 users in 100 patients treated)

Abnormal results from some blood tests

Blocked nose

Headache

Dizziness

Muscle weakness

Nausea

Pain in the abdomen (tummy)
Rash, skin redness
Uncommon (affects 1 to 10 users in 1,000 patients treated)
Asthma
Bruising
Cough
Fever
Hot flushes
Increased amount of uric acid in the blood (indicator of gout)
Itching
Sore throat
Protein in your urine
Vomiting
Tiredness
Weight gain

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Comment [piq-qrd9]: Please explain with a symptom or similar

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Tell your doctor immediately if you notice that your symptoms of the attack get worse after you received {Invented name}.

5. HOW TO STORE {INVENTED NAME}

Keep out of the reach and sight of children.

Do not use {Invented name} after the expiry date stated on the label. The expiry date refers to the last day of the month stated on the label.

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

{Invented name} should not be used if 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.

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

6. FURTHER INFORMATION

What {Invented name} contains

- The active substance is icatibant 30 mg (as acetate) in 3 ml solution for injection in each pre-filled syringe.
- The other ingredients are sodium chloride, acetic acid glacial, sodium hydroxide and water for injection. The solution does not contain any preservative.

What {Invented name} looks like and contents of the pack

{Invented name} is presented as a clear, colourless solution for injection in a pre-filled glass syringe (3 ml).

A hypodermic needle (25 G; 16 mm) is included in the package.

Marketing Authorisation Holder and Manufacturer

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