

# FYZANT

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ In Australia, 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](http://www.tga.gov.au/reporting-problems).

### 1. Why am I using FYZANT?

FYZANT contains the active ingredient icatibant. FYZANT is used for treating the symptoms of an acute attack of hereditary angioedema (HAE) in adults, adolescents and children aged 2 years and older.

For more information, see Section [1. Why am I using Fyzant?](#) in the full CMI.

### 2. What should I know before I use FYZANT?

Do not use if you have ever had an allergic reaction to icatibant or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use FYZANT?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with FYZANT and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use FYZANT?

Your doctor will determine the exact dose of FYZANT and will tell you how often it should be used. Please see step-by-step instructions for injecting FYZANT in children and adolescents.

More instructions can be found in Section [4. How do I use FYZANT?](#) in the full CMI.

### 5. What should I know while using FYZANT?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Tell your doctor immediately if you notice that your symptoms of the attack get worse after you use FYZANT.</li><li>• Remind any doctor, dentist or pharmacist you visit that you are using FYZANT.</li><li>• Tell your doctor immediately if you become pregnant while using this medicine</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not breastfeed for 12 hours after you have used Icatibant Lupin, if you are breastfeeding.</li><li>• Do not have more than 3 injections in a 24-hour period and more than 8 injections in month.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Do not drive or operate any machinery if you feel tired or dizzy as a result of your HAE attack or after using FYZANT.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep your medicine in a cool dry place where the temperature stays below 25°C. Do not freeze it.</li><li>• Keep your medicine in the original pack until it is time to use them.</li><li>• Keep this medicine where children cannot reach it.</li></ul> <p>A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.</p>

For more information, see Section [5. What should I know while using FYZANT?](#) in the full CMI.

### 6. Are there any side effects?

Almost all patients receiving FYZANT will experience a reaction at the site of the injection. Tell your doctor or pharmacist if you notice 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)).

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



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](http://www.tga.gov.au/reporting-problems).

# FYZANT

**Active ingredient(s):** Icatibant acetate

## Consumer Medicine Information (CMI)

This leaflet provides important information about using FYZANT. **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 FYZANT.**

**Where to find information in this leaflet:**

- [1. Why am I using Fyzant?](#)
- [2. What should I know before I use Fyzant?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Fyzant?](#)
- [5. What should I know while using Fyzant?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using FYZANT?

FYZANT contains the active ingredient icatibant.

FYZANT 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. Icatibant blocks the activity of bradykinin and therefore, helps reduce the symptoms of an HAE attack.

## 2. What should I know before I use FYZANT?

### Warnings

**Do not use FYZANT if:**

- you are allergic to icatibant, or any of the 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 FYZANT to a child under 2 years of age or weighing less than 12 kg. FYZANT 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 FYZANT 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 FYZANT, talk to your doctor.
- Always check the ingredients to make sure you can use this medicine.

### Check with your doctor if you:

- are suffering from angina (reduced blood flow to the heart muscle)
- you have recently suffered a stroke
- 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.
- take any medicines for any other condition
- Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Your doctor will discuss the possible risks and benefits of using FYZANT during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known whether FYZANT passes into your breast milk.

### 3. What if I am taking other medicines?

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

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

Food and drink have no effect on the action of FYZANT.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect FYZANT.**

### 4. How do I use FYZANT?

#### How much to take/use

##### Adults:

The recommended dose of FYZANT 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 FYZANT (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 FYZANT (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 FYZANT 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. FYZANT may be administered by a healthcare professional.

Follow the instructions provided and use FYZANT until your doctor tells you to stop.

#### When to take / use FYZANT

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

### How to take Fyzant

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

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

##### Adults:

FYZANT injections are usually administered by healthcare professionals. If you wish to inject FYZANT 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 FYZANT.**

**Immediately after you self-inject FYZANT or your caregiver injects you with FYZANT 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 FYZANT; 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 FYZANT 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:

FYZANT 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 FYZANT to the child.**

**Immediately after administering FYZANT 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 FYZANT; 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.

**Please see step-by-step instructions for the dose to inject in children and adolescents.**

### Step-by-step instructions for injecting FYZANT

#### 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 FYZANT, 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 FYZANT should only be made by a physician experienced in the diagnosis and treatment of HAE.

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

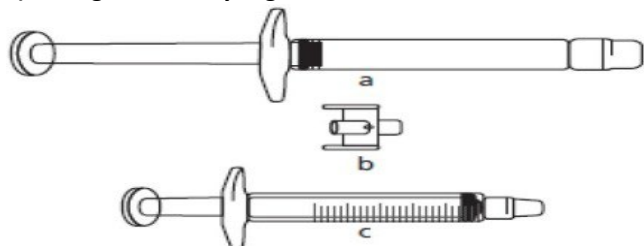
#### Important information for healthcare professionals and caregivers:

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

a) FYZANT 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:**

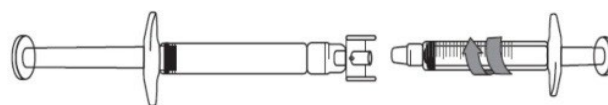
Body weight	Injection volume
12 kg to 25 kg	1.0 mL
26 kg to 40 kg	1.5 mL
41 kg to 50 kg	2.0 mL
51 kg to 65 kg	2.5 mL

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.**

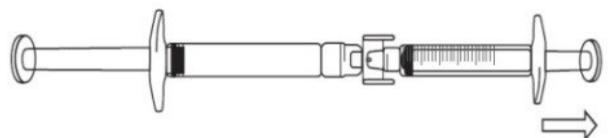
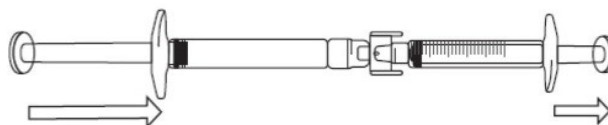
#### Preparing to extract dose less than 3 mL:

- 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 FYZANT solution to the graduated syringe:

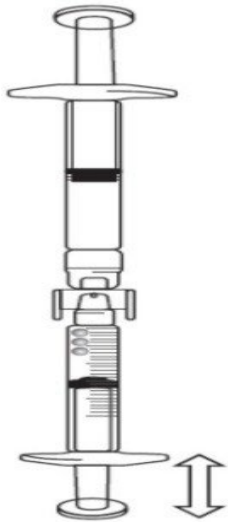
- To start transfer of FYZANT solution, push the pre-filled syringe plunger (on far left of the below image).
- If the FYZANT solution does not begin to transfer to the graduated syringe, pull slightly on the graduated syringe plunger until the FYZANT solution starts to flow into the graduated syringe (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).



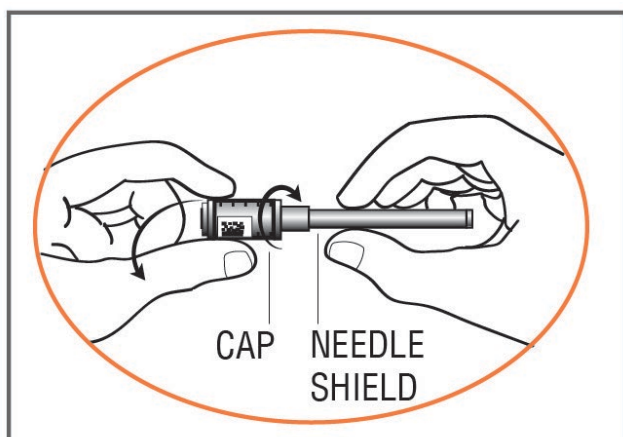
- Push the plunger of the graduated syringe so that any air is transferred back into the prefilled syringe (this step may need to be repeated several times).
- Withdraw the required volume of FYZANT solution.

**After transfer of FYZANT 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.

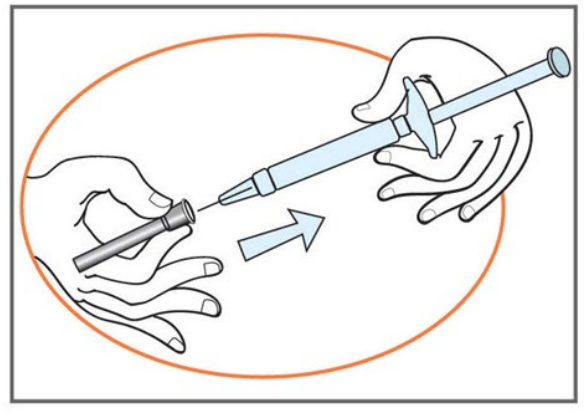
**2b). Preparing the syringe and needle for injection: All patients (adults, adolescents and children)**

- Remove the needle cap from the blister.
- Hold the needle in both hands and rotate both the hands opposite to each other to break the seal.
- Remove the plastic cap from back of the needle (the needle should still be in the needle shield).



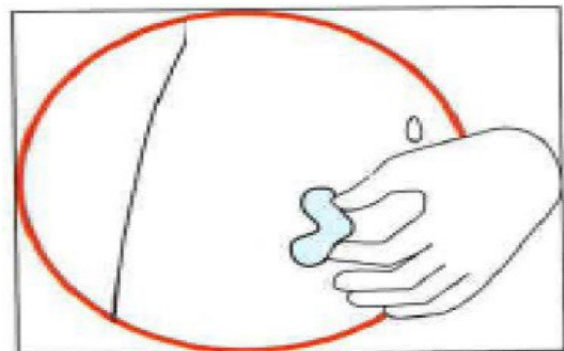
- Grip the syringe firmly. Carefully attach the needle to the syringe containing the colourless solution.
- Screw the syringe on the needle still fixed in the needle cap.
- Remove the needle from the needle cap by pulling the syringe. Do not pull up on the plunger.

- The syringe is now ready for injection.



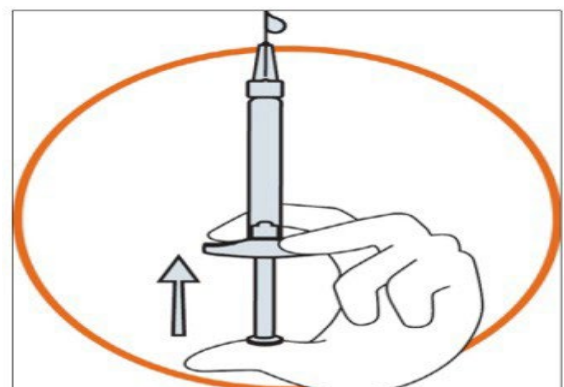
**3. Preparing the injection site**

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

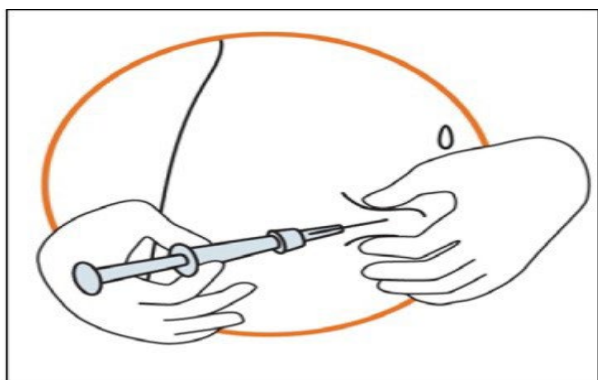


**4. Injecting the solution**

- 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 the syringe between a 45 to 90 degrees angle to your skin with the 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 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.

### If you use too much FYZANT

If you think that you have used too much FYZANT, you may need urgent medical attention.

When high doses have been given, patients have experienced a drop in blood pressure.

**You should immediately:**

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Accident and Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using FYZANT?

### Things you should do

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

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

If you are about to be started on any new medicine, remind your doctor, dentist or pharmacist that you are taking FYZANT.

### Call your doctor straight away if you:

- find out or suspect that you are pregnant.

Remind any doctor, dentist or pharmacist you visit that you are using FYZANT.

### Things you should not do

#### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how FYZANT affects you.**

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

#### Drinking alcohol

**Tell your doctor if you drink alcohol.**

Alcohol may interfere with the way this medicine works.

#### Looking after your medicine

- 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 FYZANT 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 this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

#### Getting rid of any unwanted medicine

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. Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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

Almost all patients receiving FYZANT 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 FYZANT. Mostly, these are mild and short-lived.

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

### What FYZANT contains

<b>Active ingredient (main ingredient)</b>	<ul style="list-style-type: none"><li>• Icatibant acetate (equivalent to 30 mg of icatibant)</li></ul>
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<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• Sodium chloride</li><li>• Acetic acid, glacial (for pH adjustment)</li><li>• Sodium hydroxide (for pH adjustment)</li><li>• Water for injections</li><li>• Nitrogen</li></ul> <p>The injection solution contains less than 1 mmol (23 milligrams) of sodium so it is essentially 'sodium free'.</p>
<b>Potential allergens</b>	Does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

**Do not take this medicine if you are allergic to any of these ingredients.**

### What Fyzant looks like

FYZANT is supplied in one single-use pre-filled glass syringe with a grey 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.

(AUST R 355650)

### Who distributes FYZANT

Arrotex Pharmaceuticals Pty Ltd,  
15 – 17 Chapel Street,  
Cremorne,  
VIC 3121  
Australia

[www.arrotex.com.au](http://www.arrotex.com.au)

This leaflet was prepared in January 2026.