

# JETREA® RTU 0.375 mg/0.3 mL

## Solution for Intravitreal Injection

ocriplasmin

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### Consumer Medicine Information

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#### What is in this leaflet

This leaflet answers some common questions about Jetrea RTU. 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 Jetrea RTU against the benefits it is expected to have for you.

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

**Keep this leaflet with your medicine.**

You may need to read it again.

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#### What Jetrea RTU is used for

Jetrea RTU is used to treat adults with an eye disease called vitreomacular traction (VMT) including when it is associated with a small to medium macular hole in the macula (central part of the light-sensitive layer at the back of the eye).

As a person gets older, the vitreous (jelly-like material in the centre of the eye) shrinks and separates from the retina (the light-sensitive layer in the back of the eye). VMT occurs when the vitreous remains attached to the central part of the retina (called macula). The macula provides central vision that is needed for everyday tasks such as

driving, reading and recognising faces.

The symptoms of VMT include distorted, blurred or decreased vision and potentially a defect in central vision. When the disease progresses, the shrinking vitreous may pull the macula away from the back of the eye and eventually may result in the formation of a hole in the macula (called macular hole).

Jetrea RTU contains the active ingredient ocriplasmin, which works by separating the vitreous from the macula and helping to close the macular hole, if one is present, which may decrease symptoms caused by VMT.

Ocriplasmin is a form of human plasmin which is an enzyme.

Before prescribing Jetrea RTU for you, your doctor will have examined the eye and decided that Jetrea RTU is the right medicine for your eye condition.

Ask your doctor if you have any questions about why Jetrea RTU has been prescribed for you.

Jetrea RTU is not addictive.

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#### Before Jetrea RTU is given

##### *When you must not be given it*

You must not be given Jetrea RTU if:

- you have an active or suspected infection in or around your eye

- you have an allergy to ocriplasmin, or any of the ingredients listed at the end of this leaflet.

Some of the 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; rash, itching or hives on the skin.

Jetrea RTU is not for use in children.

The safety and effectiveness of Jetrea RTU in children has not been established.

If you are not sure whether you should be given Jetrea RTU, talk to your doctor.

##### *Before you start to use it*

Tell your doctor if you have or have had any of the following medical conditions and treatments:

- any condition that damages the retina (back of the eye) and causes vision to fade. Early symptoms can include poor night vision, problems seeing things in dimly lit environments, loss of peripheral (side) vision and difficulty in judging changes in peripheral vision, such as curbs or steps.
- if you suffer or have suffered from any eye diseases or have had eye laser treatment. Your doctor will decide if treatment with Jetrea RTU is right for you.
- you have been given Jetrea RTU before in the same eye. Jetrea RTU can only be administered

once to each eye. Only one eye can be injected at a time.

- any other medical conditions.

**Tell your doctor if:**

- you have an allergy to any medicines, foods, dyes or preservatives, ocriplasmin or any of the ingredients listed at the end of this leaflet:
- any condition that damages the retina (back of the eye) and causes vision to fade. Early symptoms can include poor night vision, problems seeing things in dimly lit environments, loss of peripheral (side) vision and difficulty in judging changes in peripheral vision, such as curbs or steps.
- if you suffer or have suffered from any eye diseases or have had eye laser treatment. Your doctor will decide if treatment with Jetrea RTU is right for you
- you have a history of allergic problems, including eczema, hives or hay fever
- you are pregnant or intend to become pregnant.  
Your doctor will discuss the possible risks and benefits of using Jetrea RTU during pregnancy.
- you are breast-feeding or intend to breast-feed.  
Your doctor will discuss the possible risks and benefits of using Jetrea RTU when breastfeeding.

If you have not told your doctor about any of the above, tell them before you are given Jetrea RTU.

***Using or taking other medicines***

Your doctor may ask you to use antibiotic eye drops before and after the injection in order to prevent any possible eye infections.

Tell your doctor if you are using or taking any other medicines, including anti VEGF-inhibitors or any other medicines that you buy

without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and Jetrea RTU may interfere with each other.

This is particularly important if you are currently using any eye medications or using any other type of eye drops.

Some medicines may be affected by Jetrea RTU, or may affect how well it works. You may need different amounts of your medicines or you may need to take different medicines.

Your doctor has more information on medicines to be careful with or avoid when being given Jetrea RTU.

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**How Jetrea RTU is given**

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***How much is given***

The usual dose of Jetrea RTU is 0.1 mL once in one eye only

The other eye may be treated at later time, if needed,

***How it is given***

Jetrea RTU is given as a single injection into the eye.

**It must be given by a qualified ophthalmologist (eye specialist) who has experience in giving injections into the eye.**

On the day of your surgery your doctor will:

- explain the possible effects that you may experience when you receive an injection of Jetrea RTU in the eye. These may include inflammation, infection or bleeding of the eye. An increase in eye pressure may also occur.
- use antibiotic drops and clean your eye and eyelid carefully to prevent infection.

- give you a local anaesthetic to prevent any pain from the injection.

After the injection, your doctor will monitor your vision and may perform some eye tests to make sure there are no complications. The injection might increase your eye pressure which is not noticeable to you. Your doctor will test for this, and provide any treatment if needed.

You must not be given Jetrea RTU if:

- it was not stored properly prior to use (i.e. minus 20°C ± 5°C)
- the packaging appears damaged in any way
- the expiry date on the bottle/carton has passed.

If you use this medicine after the expiry date has passed, or if it was not stored properly before use, it may not work.

Your doctor or pharmacist are responsible for storing and preparing Jetrea RTU.

***If you are given too much (overdose)***

**If you think that you have been given too much Jetrea RTU immediately tell your doctor, the Poisons Information Centre on 131126 or go to Accident and Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.**

If you are given more Jetrea RTU than you need, your doctor may measure your eye pressure and treat you if needed.

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**After Jetrea RTU is given**

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***Things you must do***

Carefully follow all directions given to you by your doctor. They may

differ from the information contained in this leaflet.

Tell all doctors and pharmacists who are treating you that Jetrea RTU has been used.

If you develop an eye infection, receive an eye injury or have eye surgery, tell your doctor.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you have been given Jetrea RTU.

### *Things to be careful of*

**The Jetrea RTU treatment may produce a significant, but short-lasting, loss of vision and visual disturbances. This may affect the ability to drive or use machines.**

Do not drive or operate machinery on the day of surgery and for the first 7 days after the use of Jetrea RTU injection.

Do not drive or operate machinery until your symptoms clear.

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## Side effects

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All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

Tell your doctor immediately if you develop the following after injection of Jetrea RTU:

- a severe decrease in vision has been reported in up to 1 in 10 patients within one week after Jetrea RTU treatment. This is generally transient and reversible, and will usually disappear without treatment.
- symptoms such as eye pain, worsening eye redness, severely blurred or decreased vision, increased sensitivity to light or an increased number of dark

floating spots in the field of vision (floaters) are also seen in up to 1 in 10 patients and may be the signs of an infection, bleeding, separation or tear of the retina or an increase in the pressure inside the treated eye.

Talk to your doctor if you develop any of the additional side effects listed below:

**Very common side effects** (may affect more than 1 in 10 patients)

- dark floating spots in the field of vision (floaters)
- eye pain
- bleeding on the surface of the eye
- color vision changes

**Common side effects** (may affect up to 1 in 10 patients)

- decreased vision which may be severe
- visual disturbances
- decreased vision or blind spots in parts of the field of view
- blurred vision
- bleeding inside the eye
- blind spot or blind area in the centre of the vision
- distorted vision
- swelling of the surface of the eye and of the eyelid
- inflammation of the eye
- flashes of light in the eye
- eye redness
- irritation on the surface of the eye
- dry eye
- feeling of having something in the eye
- itching of the eye
- eye discomfort
- sensitivity to light
- increased tear production

**Uncommon side effects** (may affect up to 1 in 100 patients):

- transient severe decreased vision
- difficulty in seeing well at night or in dim light
- disturbance in your eye's reaction to the light that may

increase your sensitivity to light (pupillary reflex impaired)

- double vision
- accumulation of blood in the front part of the eye
- abnormal constriction of the pupil (black part in the centre of the eye)
- different sized pupils
- a scratch or scrape of the cornea (transparent layer that covers the front of the eye)

Some tests and imaging of the back of the eye (retina) have been found to be abnormal after Jetrea administration

Some effects (such as flashes, floaters) can also be perceived from the untreated eye in some cases.

If you get any side effects, talk to your doctor.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- fast or irregular heartbeat, also called palpitations
- dizziness or lightheadedness
- skin rash or itching
- swelling of the hands, feet, ankles or legs
- wheezing or difficulty in breathing
- shortness of breath
- swelling of the face, lips, mouth
- very slow pulse or chest pain
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in breathing or swallowing
- severe and sudden onset of pinkish, itchy swellings on the skin, also called hives or nettle rash.

These hypersensitivity reactions can be very serious side effects. You may need urgent medical attention or hospitalisation.

**These side effects are very rare.**

Other side effects not listed may also occur in some patients. Tell

your doctor if you notice any other effects

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## After Jetrea RTU is used

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### *Storage*

Jetrea RTU should be stored in a freezer at minus  $20^{\circ}\text{C} \pm 5^{\circ}\text{C}$ .

Protect from light.

Information about storage of Jetrea RTU is provided to your doctor and pharmacist.

They are responsible for correctly storing Jetrea RTU. It is unlikely that you will be required to store Jetrea RTU.

### *Disposal*

Your doctor or pharmacist are responsible for the appropriate disposal of any unused Jetrea RTU.

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## Product description

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### *What it looks like*

Jetrea RTU is a clear and colourless solution for injection that comes in a glass vial.

### *Ingredients*

Jetrea RTU contains the active ingredient ocriplasmin 0.375 mg in 0.3 mL.

Jetrea RTU also contains:

- sodium chloride
- citric acid
- mannitol
- sodium hydroxide
- hydrochloric acid
- purified water.

The pH of the solution may be adjusted with sodium hydroxide and/or hydrochloric acid.

### *Supplier*

Jetrea RTU is supplied in Australia by:

I-Care Pharma Distributors Pty Ltd  
Unit 3/92A Mona Vale Road  
Warriewood NSW 2102.

### *Date of preparation*

This leaflet was prepared in July 2019.

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