JETREA*

Concentrated Solution for Intravitreal Injection after Dilution

(ocriplasmin 0.5 mg/0.2 mL)

Consumer Medicine Information

What is in this Leaflet

This leaflet answers some common questions about **JETREA*.** 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** 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.

What is JETREA used for?

JETREA 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 macular (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 contains active ingredient called 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** for you, your doctor will have examined the eye and decided that **JETREA** is the right medicine for your eye condition.

Ask your doctor if you have any questions about why **JETREA** has been prescribed for you.

JETREA is not addictive.

Before you are given JETREA

When you must not be given it

You must not be given JETREA if:

- you have an active or suspected infection in or around your eye
- you have an allergy to ocriplasmin, citric acid, mannitol or sodium hydroxide

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.

You must not be given JETREA if you are a child.
The safety and effectiveness of **JETREA** in children has not been established.

If you are not sure whether you should be given **JETREA,** talk to your doctor.

Before you are given 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** is right for you.
- you have been given **JETREA** before in the same eye. **JETREA** 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, JETREA, ocriplasmin or any of the ingredients listed at the end of this leaflet**
- **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** during pregnancy.
- **you are breastfeeding or intend to breastfeed**
  Your doctor will discuss the possible risks and benefits of using **JETREA** when breastfeeding.

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

Using 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 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** may interfere with each other.

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

Some medicines may be affected by **JETREA,** 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.**

How JETREA is given

How much is given

The usual dose is 0.1 mL of the diluted **JETREA** solution (0.125 mg) once in one of the eyes.

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

How it is given

JETREA 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 the injection, your doctor may use antibiotic drops and clean your eye and eyelid carefully to prevent infection. Your doctor will also 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 if:

- it was not stored properly prior to use (ie minus 20°C ± 5°C)
- it was not used within 15 minutes after reconstitution
- 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.

If you are given too much (overdose)

If you are given more **JETREA** than you need, your doctor may measure your eye pressure and treat it if needed.

If you think that you have been given too much JETREA, immediately tell your doctor or telephone the Poisons Information Centre (in Australia, call 13 11 26; in New Zealand, call 0800 POISON or 0800 764 766) for advice or go to Accident & Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

After you are given JETREA

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 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.

Things to be careful of

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

This is most likely to occur during the first 7 days after the injection due to the JETREA working in the eye.

If you experience these signs, you must not drive or use machines until these temporary visual disturbances subside.

Side effects

Tell your doctor as soon as possible if you do not feel well after the injection of JETREA.

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.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor **immediately** if you develop any of the following after injection of JETREA:

- a severe decrease in vision has been reported in up to 1 in 10 patients within one week after JETREA 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
- colour vision changes

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

- decreased sharpness of vision
- decrease in 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 vision
- inflammation of the eye
- distorted vision
- swelling of the surface of the eye
- swelling of the eyelid
- flashes of light in the eye
- eye redness
- irritation on the surface of the eye
- dry eye
- itching of the eye
- a feeling of having something in 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 may increase your sensitivty to ligh (pupillary reflex impaired)
- double vision
- accumulation of blood in the front part of the eye
- abnormal constriction of the pupil (black part of the centre of the eye)
- different sized pupils
- a scratch or scrape on the cornea (transparent layer that covers the front part 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. This includes any possible side effects.

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

- fast or irregular heartbeats, also called palpitations
- dizziness and light-headedness
- skin rash, itching
- swelling of the hands, feet, ankles or legs
- wheezing, difficulty in breathing
- shortness of breath
- skin rash
- very slow pulse, chest pain
- fainting
- 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.

After using JETREA

Storage

It is not likely that you will be required to store JETREA.

JETREA should be stored in a freezer at minus 20°C ± 5°C.

Protect from light.

Information about storage and preparation of JETREA is provided to healthcare professionals only.

Your doctor or pharmacist are responsible for storing and preparing JETREA. They are also responsible for disposing any unused JETREA correctly.

Product description

What it looks like

JETREA is a concentrate for solution for injection in a glass vial.

The concentrate is clear and colourless. Each pack contains one vial containing 0.5 mg of ocriplasmin in 0.2 mL.

After dilution with 0.2 mL of sodium chloride solution, 0.1 mL of the diluted solution contains 0.125 mg of ocriplasmin.

Ingredients

Active ingredients:

- ocriplasmin 2.5 mg/mL

Other ingredients:

- citric acid
- mannitol
- sodium hydroxide
- purified water

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

Supplier

In Australia, this product is supplied by:

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

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