

Jetrea

Ocriplasmin 0.5 mg/0.2 ml concentrate for solution for injection

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What Jetrea is used for

Jetrea contains the active substance ocriplasmin.

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

VMT is caused by traction resulting from a persistent attachment of the vitreous humour (jelly-like material in the back of the eye) to the macula. The macula provides central vision that is needed for everyday tasks such as driving, reading and recognising faces. VMT can cause symptoms such as distorted or decreased vision. When the disease progresses the traction may eventually result in the formation of a hole in the macula (called a macular hole).

How Jetrea works

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

Before you use Jetrea

You must not be given Jetrea

-if you are allergic to ocriplasmin or any other ingredients of this

medicine (listed in Product Description);

-if you have (or suspect you may have) an infection in or around your eye.

Talk to your doctor/ophthalmologist before you are given Jetrea.

Jetrea is given as an injection into the eye. Your doctor/ ophthalmologist will monitor you in case you develop an infection or any complications after the injection. You should contact your doctor/ ophthalmologist immediately if you develop any of the eye symptoms described in "Side Effects", after an injection of Jetrea.

You will not be given Jetrea into both eyes at the same time.

You will not be given Jetrea more than once into the same eye.

Tell your doctor/ophthalmologist if you have or have had any eye conditions or eye treatments. Your doctor/ophthalmologist will decide if treatment with Jetrea is right for you.

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

Inform your doctor/ophthalmologist if you have had an injection of a medicine into the eye recently. This information will be taken into account to evaluate if and when Jetrea can be injected into the same eye.

How to use Jetrea

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

Jetrea is given as a single injection into the affected eye. The recommended dose is 0.125 mg.

Jetrea is given one time only for one eye.

Your doctor/ophthalmologist may ask you to use antibiotic eye drops before and after the injection in order to

prevent any possible eye infection.

On the day of the injection, your doctor/ophthalmologist will use antimicrobial eye drops and clean your eye and eyelid carefully to prevent infection. Your doctor/ophthalmologist will also give you a local anaesthetic to prevent any pain from the injection.

After the injection, your doctor/ophthalmologist will monitor your vision.

The information on the effects of Jetrea overdose is limited. If an overdose occurs, your doctor/ ophthalmologist will monitor your vision closely.

If you have any further questions on the use of this medicine, ask your doctor/ophthalmologist.

While you are using Jetrea

Jetrea is given as an injection into the eye. Your doctor/ophthalmologist will monitor you in case you develop an infection or any complications after the injection. You should contact your doctor/ophthalmologist immediately if you develop any of the eye symptoms described in section 'side effects', after an injection of Jetrea.

After Jetrea treatment you may experience some decrease in vision for a limited amount of time. If this happens, do not drive or use any tools or machines until your vision improves.

Side effects

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

Contact your doctor or ophthalmologist immediately if you develop **any of the following symptoms** 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 reversible and will usually disappear within two weeks.

Symptoms such as eye pain, **worsening** eye redness, **severely** blurred or decreased vision, **increased** sensitivity to light or **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.

Symptoms such as fluctuation of vision, double vision, headache, halos around light, nausea and vomiting have been reported in up to 1 in 100 patients and may be the signs of a displacement or wobbling of the lens in the eye from its normal position.

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

- bleeding on the surface of the eye

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

- visual disturbances
- bleeding inside the eye
- blind spot or blind area in the field of vision
- distorted vision
- swelling of the surface of the eye
- swelling of the eyelid
- inflammation of the eye
- flashes of light in the eye
- irritation on the surface of the eye
- dry eye
- a feeling of having something in the eye
- itching of the eye
- eye discomfort
- colour vision changes

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

- decreased vision in parts of the field of view
- 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)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers -> Reporting)

Storage and Disposal of Jetrea

Store in a freezer (-20°C ±5°C). If the product is exposed to higher temperatures during storage, the vial should be discarded.

The solution should be used immediately after dilution. The vial and any unused portion of the diluted solution should be discarded after single use.

Product Description

The active substance is ocriplasmin. One vial of Jetrea contains 0.5mg of ocriplasmin in 0.2ml solution. After dilution with 0.2ml of sodium chloride solution, 0.1ml of the diluted solution contains 0.125mg of ocriplasmin.

The other ingredients are mannitol, citric acid, sodium hydroxide and water for injections.

Jetrea is a concentrate for solution for injection in a vial. The concentrate is clear and colourless. Each pack contains one vial.

Registration number:
MALXXXXXXXXA

Manufacturer

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Product Registration Holder

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