

Here's what you need to know about your Treatment with JETREA® (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.¹



JETREA®

(ocriplasmin)
Concentrate for solution
for injection, 0.5mg/0.2ml

Introduction

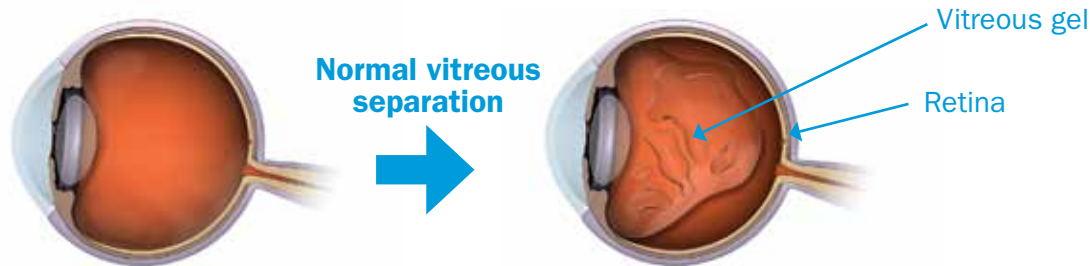
- You have been given this booklet because your doctor/ophthalmologist (eye specialist) believes you are suitable for treatment with a medicine called JETREA® (ocriplasmin)
- JETREA® is used to treat adults with an eye disease called vitreomacular traction (VMT), including when it is associated with a small hole in the macula¹ (central part of the light-sensitive layer at the back of the eye)
- This booklet has been created to help you understand more about VMT, the administration of JETREA® and what to expect in the days after treatment (including any potential side-effects)
 - If you have any questions or concerns about any information provided in this booklet, or about the product, please discuss these with your doctor/ophthalmologist before receiving your JETREA® treatment



What Are Vitreomacular Traction and Macular Hole?

- As people get older, the vitreous humour (jelly-like material inside the eye that helps it maintain a round shape) detaches naturally from the retina (the light-sensitive layer of tissue located at the back of the eyeball)²

The eye showing complete separation of the vitreous humour from the retina, a process which occurs naturally with ageing

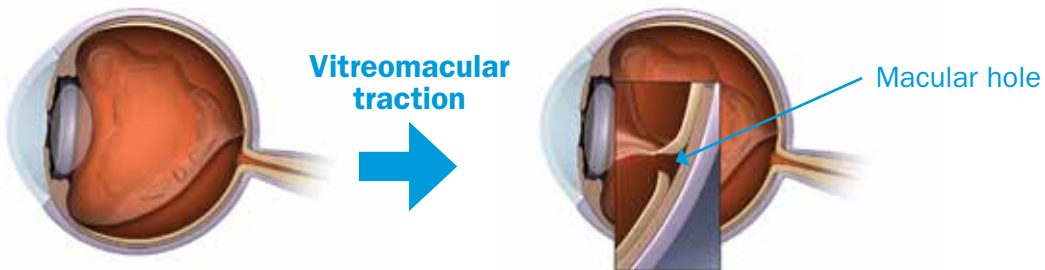


- However, every now and then, the vitreous humour remains attached to some areas of the retina, particularly at the macula (the area of the retina responsible for central vision needed for everyday tasks such as driving, reading and recognizing faces). This is known as vitreomacular adhesion²

The eye showing persistent attachment of the vitreous humour to the macula



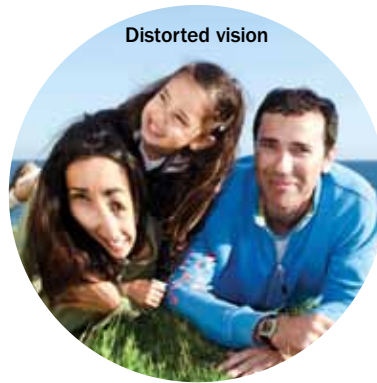
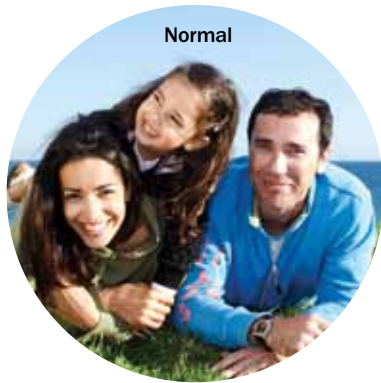
- These areas of vitreomacular adhesion can exert a 'pulling force' on the macula, a condition known as vitreomacular traction, or VMT^{1,2}
- The consequences of this pulling or 'traction' depend on where and how firmly the vitreous remains attached²



- VMT may eventually lead to the formation of a hole in the macula^{1,2}

How Can Vitreomacular Traction and Macular Hole Affect Your Vision?

- VMT may cause symptoms such as:^{2,3}
 - Distorted vision
 - Decreased visual acuity (sharpness of vision)
- In some individuals, VMT leads to macular hole, the symptoms of which may include the appearance of a blind spot in the centre of the field of vision



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How Are Cases of Vitreomacular Traction and Macular Hole Diagnosed?

- VMT can be diagnosed using a technique known as optical coherence tomography (OCT)
 - OCT is a non-invasive scan that produces detailed images of the inside of the eye⁴
 - OCT allows the doctor/ophthalmologist to look closely for signs of VMT and macular hole^{5,6}

What is JETREA®?

- JETREA® is a synthetic form of the human enzyme plasmin, which is produced using DNA technology
 - In addition to the active substance ocriplasmin, JETREA® contains mannitol, citric acid, sodium hydroxide and water. JETREA® is also mixed with sodium chloride solution prior to injection¹
- JETREA® works by separating the vitreous from the macula, releasing VMT and helping to close the macular hole (if present)¹

How to Prepare for Treatment with JETREA®

- JETREA® is given as a one-time, single injection into the eye — a procedure known as an intravitreal injection
- Although the thought of such an injection may be concerning, the anticipated level of discomfort may be considerably greater than that experienced during the actual procedure⁷
 - A study has shown that most patients do not experience any discomfort during the intravitreal injection procedure, with the other patients reporting only mild discomfort⁷
- You may feel a little pressure when the injection is given
- To help prevent any infection, your doctor/ophthalmologist may ask you to use antibiotic eye drops before the injection¹
- You may wish to ask a friend or family member to accompany you on the day of the procedure because your vision in the injected eye may be temporarily affected after the treatment



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- **Before receiving JETREA[®], it is important to tell your doctor/ophthalmologist if you:**

- Think you may be allergic to any of the ingredients in JETREA[®] (listed on page 6)¹, have any known allergies or have had reactions after any other eye treatments
 - Have or suspect you may have an infection in or around your eye, or other serious infection¹
 - Have ever had any problems or diseases of the eye or eye treatments¹
 - Are taking, have recently taken or expect to be taking any other medicines in the near future¹
 - Have had an injection of a medicine into the eye recently¹
 - Are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby¹
- JETREA[®] **should not** be used in children and adolescents younger than 18 years of age because of the lack of data in this patient group¹



How is JETREA® Given?

- **Before you are given JETREA®, your doctor/ophthalmologist will:**^{1,8}
 - Numb your eye with an anaesthetic to help prevent pain
 - Possibly cover your face and the area around the eye with a special drape
 - Apply some antibiotic drops, and clean your eye and the skin around it
 - Hold your eye open so that you do not blink, perhaps using a device to help with this
- Your doctor/ophthalmologist will then give you the intravitreal injection of JETREA® by inserting the needle into the white part of your eye¹
- JETREA® must be given by a qualified doctor/ophthalmologist who has experience in giving injections into the eye¹
- Please talk to your doctor/ophthalmologist before you receive JETREA® to discuss any worries or concerns that you may have¹
- You will **not** receive an injection of JETREA® in both eyes at the same time and you will not be given JETREA® more than once in the same eye¹

What Are the Steps Following Treatment with JETREA®?

- After your injection you will normally be allowed to go home. However, your doctor/ophthalmologist will monitor you for up to 1 week after the injection in case you develop an infection or any complication¹. A routine follow-up appointment will be arranged for you to assess how well the medicine has worked
- Your doctor/ophthalmologist may use eye drops to help prevent infection and may ask you to continue to use these drops at home for a period of time¹



Possible Side-Effects Associated with JETREA® Treatment

- Like all medicines, JETREA® can cause side-effects, although not everybody will experience these¹
- Most side-effects that occur with JETREA® appear within 1 week after injection, are not serious and resolve within 2–3 weeks¹
- Talk to your doctor/ophthalmologist if you develop any side-effects after receiving JETREA®, including any not listed in this leaflet
- **With JETREA®, patients have experienced the following side-effects in clinical trials:¹**
 - 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

Side-effects continued on the next page.



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

- Decreased vision
- Visual disturbances
- Blurred vision
- Bleeding inside the eye
- Separation or tear of the retina
- Increase in the pressure 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
- Eye redness
- Irritation on the surface of the eye
- Dry eye
- A feeling of having something in the eye
- Itching of the eye
- Eye discomfort
- Increased sensitivity to light
- Colour vision changes

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

- Decreased vision in parts of the field of view
- Displacement or wobbling of the lens inside the eye
- 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)



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- **You may experience some reduced vision for a short time immediately after your injection¹**
 - The immediate vision loss is caused by a temporary increase in the pressure of the fluid within the eye (known as an increase in intraocular pressure)
 - It is normal to experience such symptoms with an injection of this type, and symptoms usually resolve within a few minutes¹
- **The white area of the eye, where the injection was given, will likely become red**
 - This redness is normal and it will go away after a few days
 - Contact your doctor/ophthalmologist if it does not go away within 1 week after the injection or becomes worse

When to Seek Urgent Attention from Your Healthcare Provider

- It is important that you monitor for changes in the condition of your eye in the week after the injection. **You must contact your doctor/ophthalmologist immediately** if you develop any of the following symptoms after an injection of JETREA®:¹
 - A severe decrease in vision within 1 week of JETREA® treatment. This is generally reversible and will usually disappear within 2 weeks
 - If you do experience reduced vision after injection, it is important that you do not drive, or use any tools or machines, until your vision improves
 - 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). These symptoms 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 may be the signs of a displacement or wobbling of the lens of the eye from its normal position
- Your doctor/ophthalmologist will monitor you (using ophthalmological tests if necessary) and take corrective measures if needed¹



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Tips and Hints to Help People Living with Vitreomacular Traction and Macular Hole

- **Monitor your own vision regularly**

- At home, take note of any changes in your vision
- Contact your doctor/ophthalmologist if you notice any changes
- Treatment might prevent further vision loss or might improve your vision

- **Dealing with changes in your vision can be difficult and it is OK to ask for support**

- Talk with family and friends about your vision and let them know if you are having any issues with normal everyday activities
- If you do not have family or friends who can help, ask your doctor/ophthalmologist about support services

Sources for patient information booklet

1. JETREA (ocriplasmin) combined Summary of Product Characteristics and Package Leaflet: January 2013.
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4. Arevalo JF, Krivoy D, Fernandez CF. How does optical coherence tomography work? Basic principles. *Retinal Angiography and Optical Tomography* 2009. 217–222.
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8. Royal College of Ophthalmologists. Guidelines for intravitreal injections procedures. 2009. Available at: http://www.rcophth.ac.uk/core/core_picker/download.asp?id=167 (accessed 17 November 2011).

 ThromboGenics®

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