

## **Your Guide to Treatment with JETREA<sup>®</sup> (Ocriplasmin)**

# Your Guide to Treatment with JETREA<sup>®</sup> (Ocriplasmin)

## Introduction

- You have been given this booklet because your doctor/ophthalmologist (eye specialist) has prescribed you a medicine called JETREA<sup>®</sup> (ocriplasmin)
- JETREA<sup>®</sup> 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<sup>1</sup> (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<sup>®</sup> 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<sup>®</sup> treatment

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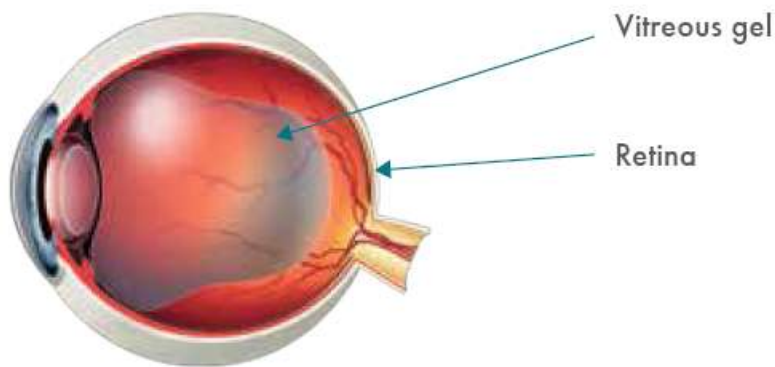
<sup>1</sup> Alcon. JETREA (ocriplasmin) combined Summary of Product Characteristics and Package Leaflet: Version supplied January 18 2013.

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## 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)<sup>2</sup>

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



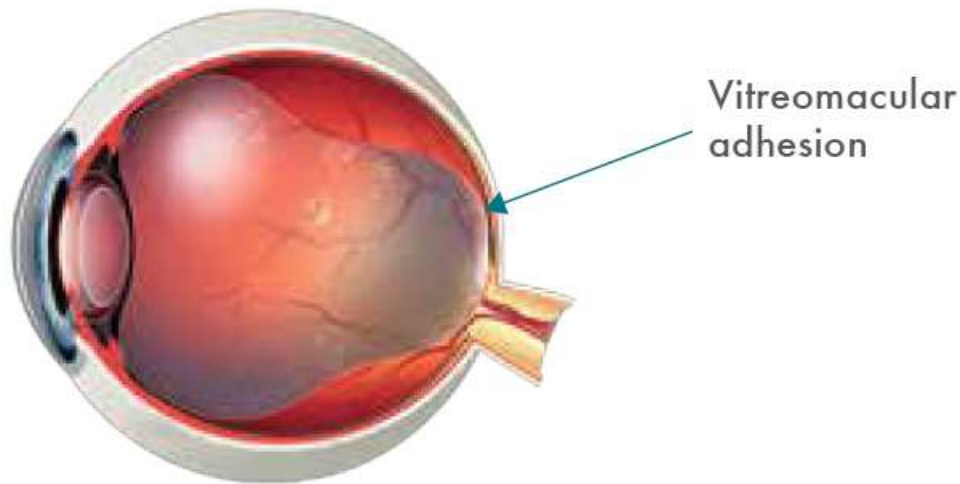
- However, every now and then, the vitreous humour remains attached to some areas of the retina, particularly at the macula (the area of the retina responsible for central vision needed for everyday tasks such as driving, reading and recognizing faces). This is known as vitreomacular adhesion<sup>2</sup>

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<sup>2</sup> Dugel PU. A new focus on the vitreous and its role in retinal function. *Retina Today* 2012;April:50–53.

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*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 VMT<sup>1,2</sup>
- The consequences of this pulling or 'traction' depend on where and how firmly the vitreous remains attached<sup>2</sup>
- VMT may eventually lead to the formation of a hole in the macula<sup>1,2</sup>

## How can Vitreomacular Traction and Macular Hole Affect Your Vision?

- **VMT may cause symptoms such as:<sup>2,3</sup>**
  - 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 or area in the centre of the field of vision

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<sup>3</sup> Hikichi T, Yoshida A, Trempe CL. Course of vitreomacular traction syndrome. *Am J Ophthalmol* 1995;119:55–61.

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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 eye<sup>4</sup>
  - OCT allows the doctor/ophthalmologist to look for signs and symptoms associated with VMT and macular hole<sup>5,6</sup>

## What Is JETREA<sup>®</sup>?

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

## How to Prepare for Treatment with JETREA<sup>®</sup>

- JETREA<sup>®</sup> is given as a single injection into the eye – a procedure known as 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 procedure<sup>7</sup>

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<sup>4</sup> Arevalo JF, Krivoy D, Fernandez CF. How does optical coherence tomography work? Basic principles. 2009. 217–222.

<sup>5</sup> Carpineto P, Di Antonio L, Aharrh-Gnama A *et al.* Diagnosing and treating vitreomacular adhesion. *Eur Ophthalmic Rev* 2011;5:69–73.

<sup>6</sup> Stalmans P. Management and intervention strategies for symptomatic vitreomacular adhesions. 2011. Available at: <http://www.retinalphysician.com/printarticle.aspx?articleID=105651> (accessed 5 December 2012).

<sup>7</sup> Chua PY, Mitrut I, Armbrrecht AM *et al.* Evaluating patient discomfort, anxiety, and fear before and after ranibizumab intravitreal injection for wet age-related macular degeneration. *Arch Ophthalmol* 2009;127:939–940.

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- A study has shown that most patients do not experience any discomfort during the intravitreal injection procedure, with the other patients reporting only mild discomfort<sup>7</sup>
- 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 injection<sup>1</sup>
- You may wish to ask a friend or family member to accompany you on the day of the procedure because your vision may be temporarily affected after the treatment
- **Before receiving JETREA<sup>®</sup>, it is important to tell your doctor/ophthalmologist if you:**
  - Think you may be allergic to any of the ingredients in JETREA<sup>®</sup> (listed on page 5 <sup>1</sup>, 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<sup>1</sup>
  - Have ever had any problems or diseases of the eye or eye treatments<sup>1</sup>
    - Are taking, have recently taken or expect to be taking any other medicines in the eye in the near future<sup>1</sup>
    - Have had an injection of a medicine into the eye recently<sup>1</sup>
  - Are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby<sup>1</sup>
- JETREA<sup>®</sup> **should not** be used in children and adolescents younger than 18 years of age because of the lack of data in this patient group<sup>1</sup>

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## How Is JETREA<sup>®</sup> Given?

- Your doctor/ophthalmologist will give you the intravitreal injection of JETREA<sup>®</sup> by inserting the needle into the white part of your eye<sup>1</sup>
- JETREA<sup>®</sup> must be given by a qualified doctor/ophthalmologist who has experience in giving injections into the eye<sup>1</sup>
- Please talk to your doctor/ophthalmologist before you receive JETREA<sup>®</sup> to discuss any worries or concerns that you may have<sup>1</sup>
- You will not receive an injection of JETREA<sup>®</sup> in both eyes at the same time and you will not be given JETREA<sup>®</sup> more than once in the same eye<sup>1</sup>
- **Before you are given JETREA<sup>®</sup>, your doctor/ophthalmologist will:**<sup>1,8</sup>
  - 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
  - Numb your eye with an anaesthetic to help prevent pain

## What Are the Steps Following Treatment with JETREA<sup>®</sup>?

- Your doctor/ophthalmologist will monitor you for up to 1 week after the injection in case you develop an infection or any complication<sup>1</sup>
- 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 time<sup>1</sup>

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<sup>8</sup> Royal College of Ophthalmologists. Guidelines for intravitreal injections procedures. 2009. Available at: [http://www.rcophth.ac.uk/core/core\\_picker/download.asp?id=167](http://www.rcophth.ac.uk/core/core_picker/download.asp?id=167) (accessed 17 November 2011).

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## Possible Side-Effects Associated with JETREA<sup>®</sup> Treatment

- Like all medicines, JETREA<sup>®</sup> can cause side-effects, although not everybody will experience these<sup>1</sup>
- Most side-effects that occur with JETREA<sup>®</sup> appear within 1 week after injection, are not serious and are resolved within 2–3 weeks<sup>1</sup>
- Talk to your doctor/ophthalmologist if you develop any side-effects after receiving JETREA<sup>®</sup>, including any not listed in this leaflet
- **With JETREA<sup>®</sup>, patients have experienced the following side-effects in clinical trials:**<sup>1</sup>
  - 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
  - Common side-effects (may affect up to 1 in 10 patients):
    - 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



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- Increased sensitivity to light
- Colour vision changes
- Uncommon side-effects (may affect up to 1 in 100 patients):
  - 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)
- **You may experience some reduced vision for a short time immediately after your injection<sup>1</sup>**
  - 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)<sup>9</sup>
  - It is normal to experience such symptoms with an injection of this type, and symptoms usually resolve within a few minutes<sup>9</sup>
- **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

## Additional Identified and Potential Risks Associated with an Intravitreal Injection of JETREA<sup>®</sup>

The following additional side-effects have been reported in clinical trials with JETREA<sup>®</sup> and are classed as identified risks. These are risks that are known to be associated with JETREA<sup>®</sup> treatment.<sup>9</sup>

- **Electroretinogram (ERG) abnormalities:** An ERG is a procedure designed to measure the electrical responses of the cells in the back of the eye. ERG abnormalities have been reported in JETREA<sup>®</sup>-treated patients; however,

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<sup>9</sup> Alcon. JETREA risk management plan. 2012.

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because this procedure was not routinely used in all clinical trials, the frequency of this side-effect is currently unknown

- **Increased VMT and/or development/progression of macular hole:** Worsening of the treated condition (i.e. VMT or macular hole) has occurred in fewer than 1 in 10 JETREA<sup>®</sup>-treated patients
- **A build-up of fluid under the retina** (known as retinal/macular edema): Reported in 1 in 10 JETREA<sup>®</sup>-treated patients

The following are classed as potential risks. These risks have not been confirmed to be associated with JETREA<sup>®</sup> in clinical trials, but are possible based on the current knowledge of the drug and its mechanism of action.<sup>9</sup>

- **Immunogenicity (the ability of a substance to cause a reaction of the body's immune system):** No immune response to a single injection of JETREA<sup>®</sup> at the recommended dose has been reported, and the potential risk of such a response occurring is considered to be low
- **Interactions with other medications:** The interaction of JETREA<sup>®</sup> with other medications has not been fully investigated in clinical trials. You must inform your doctor/ophthalmologist of any other medicines you are taking
- **Traumatic cataract** (a clouding of the lens inside the eye, caused by damage to the eye): This is a known complication of intravitreal injection, although no cases have been reported with JETREA<sup>®</sup>
- **Medication errors, including underdosing and overdosing:** Although unlikely, this is a potential risk – as with all medications

## 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<sup>®</sup>:<sup>1</sup>
  - A severe decrease in vision within 1 week of JETREA<sup>®</sup> treatment. This is generally reversible and will usually disappear within 2 weeks

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- 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 needed<sup>1</sup>

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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 – 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 at your doctor's/ophthalmologist's office about support services

**Any Adverse Drug Reactions and Medication Errors should be reported to:**

**Medicines Authority Post-licensing Directorate, 203, Level 3, Rue D'Argens, Gżira GŻR 1368, MALTA, or at: <http://www.medicinesauthority.gov.mt/adrportal>  
Telephone Number: +356 2343 9000**

Or to

Alcon Laboratories (UK) Ltd,  
☎ + 44 (0) 871 376 1402 (United Kingdom)