

Here's what you need to know about your treatment with JETREA[®] (ocriplasmin 0.375 mg/ 0.3 mL solution for injection)

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

Introduction

- You have been given this booklet because your doctor/ophthalmologist (eye specialist) has prescribed you 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)
 - 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)
 - JETREA® works by separating the vitreous from the macula, releasing VMT and helping to close the macular hole (if present)
- This booklet has been created to help you understand more about how to prepare for the treatment, the administration of JETREA®, what to expect in the days after treatment (including any potential side-effects) and when to urgently contact your doctor/ ophthalmologist
- 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

¹ JETREA SmPC. Version supplied January 2019

How to Prepare for Treatment with JETREA®

- JETREA® 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 procedure²
 - A study has shown that most patients do not experience any discomfort during the intravitreal injection procedure, with the other patients reporting only mild discomfort²
- 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 may be temporarily affected after the treatment
- **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® (In addition to the active substance ocriplasmin, JETREA® contains sodium chloride, mannitol, citric acid, sodium hydroxide, hydrochloric acid and water)¹, have any known allergies or have had reactions after any other eye treatments

² Chua PY, Mitrut I, Armbricht 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.

- Have or suspect you may have an infection in or around your eye¹
- 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 eye 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 age¹

Before you are given JETREA®, your doctor/ophthalmologist will:^{1,3}

- 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

³ Royal College of Ophthalmologists. Ophthalmic Service Guidance – Intravitreal injection therapy. 2018. Available at: <https://www.rcophth.ac.uk/wp-content/uploads/2018/02/Intravitreal-Injection-Therapy.pdf> (accessed 06 April 2018).

How is JETREA® Given?

- Your doctor/ophthalmologist will 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®?

- Your doctor/ophthalmologist will monitor you for up to 1 week after the injection in case you develop an infection or any complication¹
- 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

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®. 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

More Information on Possible Side-Effects of JETREA® Treatment

- Like all medicines, JETREA® can cause side effects, although not everybody will experience these¹
- Some tests and imaging of the back of the eye (retina) have been found to be abnormal after JETREA® administration. Your doctor will be aware of this and will take it into account when monitoring your eye
- Some effects (such as flashes, floaters) can also be perceived from the untreated eye in some cases

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)⁴
- It is normal to experience such symptoms with an injection of this type, and symptoms usually resolve within a few minutes⁴

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

- Most side-effects that occur with JETREA® appear within 1 week after injection, are not serious and are resolved within 2–3 weeks¹
- Talk to your doctor/ophthalmologist if you develop any side-effects after receiving JETREA®, including any not listed in the patient information leaflet. You can also report side effects directly via Ireland's national reporting system:
HPRA Pharmacovigilance,
Earlsfort Terrace,
IRL - Dublin 2;
Tel : +353 1 6764971,
Fax: +353 1 6762517,
Website: www.hpra.ie,
E-mail: medsafety@hpra.ie
- By reporting side effects you can help provide more information on the safety of JETREA®

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

