

[Introduction]

Welcome to your audio guide to therapy with JETREA®

You are listening to this audio guide because your doctor or ophthalmologist has prescribed you a medicine called JETREA® (also known as ocriplasmin). JETREA® is used to treat adults with an eye disease called vitreomacular traction (also known as VMT), including when it is associated with a small hole in the macula which is the 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 audio guide 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 or ophthalmologist before receiving your JETREA® treatment.

[About JETREA®]

Next, let's talk about how you can 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 procedure. 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. You may feel a little pressure when the injection is given.

In order to help prevent any infection, your doctor or ophthalmologist may ask you to use antibiotic eye drops before the injection.

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 or 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), **have any known allergies or have had reactions after any other eye treatments.** You must also inform your doctor or ophthalmologist prior to treatment if you have or suspect you may have an infection in or around your eye; if you have ever had any problems or diseases of the eye or eye treatments; if you are taking, have taken or are expecting to take medicines in the eye in the near future or if you have had an injection of a medicine into the eye recently.

Please inform your doctor or ophthalmologist if you are pregnant, think you may be pregnant, are planning to have a baby or if you are breast-feeding.

JETREA® should not be used in children or adolescents younger than 18 years of age.

Before your injection, your doctor or ophthalmologist will possibly cover your face and the area around the eye with a special drape. They will apply some antibiotic drops and clean your eye and the surrounding skin. Your eye will then be held open so that you do not blink, perhaps using a device to help with this. Your eye will then be numbed with anaesthetic to help prevent pain.

Now let's discuss how JETREA® is given

Your doctor or ophthalmologist will give you the intravitreal injection of JETREA® by inserting the needle into the white part of your eye. JETREA® must be given by a qualified doctor or ophthalmologist who has experience in giving injections into the eye. Please talk to your doctor or ophthalmologist before you receive JETREA® to discuss any worries or concerns you may have. You will not receive an injection of JETREA® in both eyes at the same time and you will not be treated with JETREA® more than once in the same eye.

Following Treatment with JETREA®, your doctor or ophthalmologist will monitor you for up to one week in case you develop an infection or any complication. Your doctor or 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.

Let us now talk about when to seek urgent attention from your healthcare provider. It is important to monitor any changes in the condition in your eye during the week after the injection.

You must contact your doctor or ophthalmologist immediately if you develop any of the following symptoms after an injection of JETREA®. A severe decrease in vision within one week of treatment with JETREA® (this is generally reversible and will usually disappear without treatment). 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 numbers of dark floating spots in the field of vision (called floaters). These 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 or ophthalmologist will monitor you, using ophthalmological tests if necessary, and will take corrective measures if needed.

Now let's hear more on the possible side-effects of JETREA® treatment. Like all medicines, JETREA® can cause side-effects, although not everybody will experience these.

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 injection. 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 minutes

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 one week after you receive the injection, are not serious and are resolved within two to three weeks.

Talk to your doctor or ophthalmologist if you develop any side-effects after receiving JETREA®, including any that were not mentioned here. Additionally, if you are in Ireland you can report side effects directly via the Health Products Regulatory Authority, Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2; Tel: +353 16764971; Fax: +353 16762517. Website: www.hpra.ie; Email: medsafety@hpra.ie.

By reporting side effects, you can help provide more information on the safety of JETREA®.

[Further tips and hints to help you live with vitreomacular traction and macular hole]

It is important to monitor your own vision regularly.

At home, take note of any changes in your vision and contact your doctor or ophthalmologist if you notice 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 or ophthalmologist's office about support services.

We hope that this information has helped you to better understand JETREA® and how it can help treat visual impairment due to VMT and macular hole. If you have further questions, please ask your doctor or ophthalmologist.