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EPAR summary for the public

Jetrea

ocriplasmin

This is a summary of the European public assessment report (EPAR) for Jetrea. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Jetrea.

For practical information about using Jetrea, patients should read the package leaflet or contact their doctor or pharmacist.

What is Jetrea and what is it used for?

Jetrea is a medicine used to treat adults with vitreomacular traction, an eye disease that can cause severe visual disturbance.

It contains the active substance ocriplasmin.

How is Jetrea used?

Jetrea is a solution for injection into the eye. It can only be obtained with a prescription and must be given by a qualified ophthalmologist (eye specialist) experienced in intravitreal injections (injections into the vitreous humour, the jelly-like material at the back of the eye). The procedure should be carried out under sterile conditions.

The recommended dose is 0.125 mg given as a single injection into the affected eye which should not be repeated. The other eye should not be treated with Jetrea for at least 7 days.

The ophthalmologist may prescribe antibiotic eye drops before and after treatment with Jetrea to prevent eye infections.

How does Jetrea work?

Vitreomacular traction is caused by vitreomacular adhesion in which the vitreous humour has an abnormally strong attachment to the central part of the retina (the light sensitive membrane at the

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back of the eye). When the vitreous humour shrinks with aging, this strong attachment results in a pulling force on the retina, which causes retinal swelling and leads to blurred or distorted vision.

The active substance in Jetrea, ocriplasmin, is similar to human plasmin, a naturally occurring enzyme in the eye which is capable of breaking down proteins between the vitreous humour and the retina which are responsible for the adhesion, thereby reducing retinal swelling and improving vision.

What benefits of Jetrea have been shown in studies?

Jetrea has been shown in studies to be effective in resolving the adhesion between the vitreous humour and the retina, reducing the need for surgery.

In two main studies involving 652 adults with vitreomacular adhesion and decreased vision, patients were given a single intravitreal injection of 0.125 mg Jetrea or a placebo injection (a dummy treatment). After 28 days, the results were that adhesions had cleared in 25% and 28% of patients who were given Jetrea injection (61 out of 219 and 62 out of 245), compared with 13% and 6% of those who received placebo (14 out of 107 and 5 out of 81). Successful treatment of vitreomacular adhesion can help reverse disturbances of the vision caused by vitreomacular traction, and prevent further loss of vision from untreated and progressive traction at the retina.

What are the risks associated with Jetrea?

The side effects seen with Jetrea affect the eye. The most common side effects are vitreous floaters (small, often irregular, dark shapes in the field of vision), eye pain, photopsia (flashes of light in the field of vision) and chromatopsia (changes in colour perception), as well as conjunctival haemorrhage (bleeding of the membrane that lies over the white part of the eye). For the full list of all side effects reported with Jetrea, see the package leaflet.

Jetrea must not be used in patients who have or are thought to have infections in or around the eyes. For the full list of restrictions, see the package leaflet.

Why is Jetrea approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that the benefits of Jetrea outweigh its risks and recommended that it be approved for use in the EU. Studies have shown that Jetrea was effective in treating vitreomacular adhesion and it is therefore expected to be effective in preventing worsening of vision which may occur with untreated and progressive vitreomacular traction. Although the effects shown were modest (resolution of vitreomacular adhesion in a quarter of patients), they were considered to be significant as treatment may improve vision and prevent the need for surgery. Regarding its safety, the most common side effects were short-lived and considered manageable, and often occurred as a response to the injection procedure or were linked to the resolution of the disease itself. The risk of more serious side effects such as decreased vision that is non-reversible, other changes to the retinal function or supporting structures of the lens appear to be small.

What measures are being taken to ensure the safe and effective use of Jetrea?

The company that markets Jetrea must ensure that all healthcare professionals who are expected to use Jetrea receive the summary of product characteristics for the medicine as well as an information pack to be given to patients.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Jetrea have also been included in the summary of product characteristics and the package leaflet.

Other information about Jetrea

The European Commission granted a marketing authorisation valid throughout the European Union for Jetrea on 13 March 2013.

The full EPAR for Jetrea can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Jetrea, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 12-2016.