

April 30, 2020

IMPORTANT PRODUCT INFORMATION

Product Discontinuation: JETREA®(ocriplasmin) injection, for Intravitreal Injection

Dear Healthcare Professional,

As part of a global transfer of commercial rights for JETREA, the decision has been taken to discontinue the manufacture for the United States and cease the commercialization of JETREA in this market, effective May 31, 2020.

The decision to discontinue the sale of JETREA is being taken for business reasons and is not because of any safety or efficacy concerns.

NDC	Name	Description	Current Lot/Expiry
24856-002-01	JETREA®(ocriplasmin) injection, for Intravitreal Injection	Each vial of JETREA contains 0.375mg ocriplasmin in 0.3mL preservative-free, citric-buffered solution (1.25mg/mL).	214151B 1/31/2021

Because May 31, 2020 falls on a Sunday and JETREA can only be ordered Monday through Thursday for overnight delivery Tuesday through Friday, Healthcare professionals can continue to order JETREA until end of business on Thursday May 28, 2020. JETREA can be used until the end of the expiry date, which is January 31, 2021.

Return Goods Policy

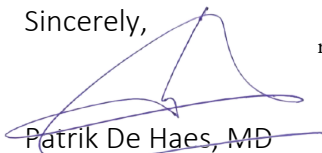
The ThromboGenics Return Goods Policy will continue to apply to this product until July 30, 2020. If you would like to return product, please do so following standard policy. If you have any questions about returns, please contact JetreaCare in advance so that you can return the product before the July 30, 2020 deadline as returns will not be accepted after that date.

Adverse Events/Medical Questions

For reporting of any adverse events or if you have medical-related questions, please email medicalinformationUS@oxurion.com or contact (855) TRY-JETREA (879-5387) [Option 2].

Sincerely,

ViBio bvba
 represented by Dr. P. De Haes
 Managing Director



Patrik De Haes, MD
 President

For current full prescribing information please see www.jetrea.com.

OCRVMA0368
 04/2020

Indication

JETREA_R (ocriplasmin) injection, for Intravitreal Injection, 1.25 mg/mL is a proteolytic enzyme indicated for the treatment of symptomatic vitreomacular adhesion.

Important Safety Information

Warnings and Precautions

- A decrease of ≥ 3 line of best corrected visual acuity (BCVA) was experienced by 5.6% of patients treated with JETREA and 3.2% of patients treated with vehicle in the controlled trials. The majority of these decreases in vision were due to progression of the condition with traction and many required surgical intervention. Patients should be monitored appropriately.
- Intravitreal injections are associated with intraocular inflammation / infection, intraocular hemorrhage and increased intraocular pressure (IOP). Patients should be monitored and instructed to report any symptoms without delay. In the controlled trials, intraocular inflammation occurred in 7.1% of patients injected with JETREA vs. 3.7% of patients injected with vehicle. Most of the post-injection intraocular inflammation events were mild and transient. If the contralateral eye requires treatment with JETREA, it is not recommended within 7 days of the initial injection in order to monitor the post injection course in the injected eye.
- Potential for lens subluxation.
- In the controlled trials, the incidence of retinal detachment was 0.9% in the JETREA group and 1.6% in the vehicle group, while the incidence of retinal tear (without detachment) was 1.1% in the JETREA group and 2.7% in the vehicle group. Most of these events occurred during or after vitrectomy in both groups.
- Dyschromatopsia (generally described as yellowish vision) was reported in 2% of all patients injected with JETREA. In approximately half of these dyschromatopsia cases there were also electroretinographic (ERG) changes reported (a- and b-wave amplitude decrease).

Adverse Reactions

- The most commonly reported reactions ($\geq 5\%$) in patients treated with JETREA were vitreous floaters, conjunctival hemorrhage, eye pain, photopsia, blurred vision, macular hole, reduced visual acuity, visual impairment, and retinal edema.

09/2017
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