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30th March 2015

# JETREA (ocriplasmin) – No dilution prior to injection of the new 0.375 mg/0.3 mL solution for injection

Dear Healthcare Professional,

ThromboGenics and Alcon corporations would like to inform you of the following:

## Summary


- JETREA 0.375 mg/0.3 mL solution for injection is a new formulation replacing JETREA 0.5 mg/0.2 mL concentrate for solution for injection. **The new formulation does not require dilution prior to injection.**

- When administering the new solution for injection formulation, healthcare professionals are required to **take the recommended injection volume of 0.1 mL directly from the vial**.

- Any dilution of the new formulation by mistake will lead to patients receiving half the recommended dose, potentially resulting in a suboptimal therapeutic effect.


The information in this letter has been reviewed and endorsed by the European Medicines Agency (EMA) and the Malta Medicines Authority.

**Further information on the safety concern and the recommendation**

In order to minimise the risk of confusion with the old concentrate formulation, the packaging of the new formulation of JETREA has a different design with a green outer carton and vial label and a blue flip-off cap.

The final injection volume of 0.1 mL and dose of 0.125 mg ocriplasmin remain unchanged. For the new formulation, only 0.1 mL of the total 0.3 mL solution in the vial should be used for administration. Any excess volume should be expelled prior injection.

After thawing, the unopened vial of the new solution for injection in the original carton protected from light may be stored in a refrigerator (2°C to 8°C) for up to 1 week. The new in-use expiry date should be calculated and noted on the carton before it is placed in the refrigerator.

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**Further information**

The indication for JETREA is for treatment of adults with vitreomacular traction (VMT), including when associated with macular hole of a diameter less than or equal to 400 microns.

For more information on the new formulation, please refer to the JETREA 0.375 mg/0.3 mL solution for injection Summary of Product Characteristics, Labeling and Package Leaflet found at www.ema.europa.eu or at www.medicinesauthority.gov.mt.

Educational brochures for patients will be made available to Healthcare Professional for distribution to all patients treated with JETREA 0.375 mg/0.3 mL solution for injection.

**Call for reporting**

This medicinal product is subject to additional monitoring, as it contains the active ingredient, ocriplasmin, which is listed on the European list of medicines as it is a new active substance authorised in the EU after 1 January 2011.

## Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed below:
ADR Reporting
The Medicines Authority
Post-Licensing Directorate
203 Level 3, Rue D'Argens
GZR 1368 Gzira
Website: www.medicinesauthority.gov.mt
Email: postlicensing.medicinesauthority@gov.mt

**Company contact point**

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