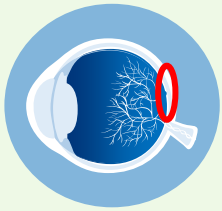


Patient Brochure

Central Serous Retinopathy (CSR) in Patients Receiving Erdafitinib Treatment

Eye problems are common when taking erdafitinib and can include dry or inflamed eyes, inflamed cornea (front part of the eye), and disorders of the retina, an internal part of the eye. This can include a condition called **Central Serous Retinopathy (CSR)**.¹

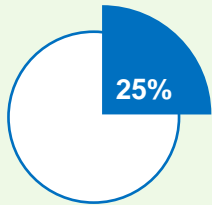
What is central serous retinopathy (CSR)?^{2,3}



CSR affects the retina, the light sensitive part of the eye.

- Fluid builds up behind the retina causing a bubble-like swelling in the eye which may lead to changes in vision.

CSR has been observed during erdafitinib treatment¹



- CSR was reported in approximately 25%, or 1 out of every 4 patients treated with erdafitinib.
- For patients who experience CSR with erdafitinib, symptoms generally occur 50 days after starting treatment.
- A severe decrease in vision was reported in approximately 3%, or 3 out of every 100 patients treated with erdafitinib.
- The majority of people who reported CSR with erdafitinib regained most or all of their vision after appropriate adjustment to their erdafitinib treatment.
- If you have additional questions about CSR, please speak to your oncologist or eye care specialist.

Tell your oncologist immediately if you experience any of these symptoms of CSR during your erdafitinib treatment:¹



Blurred vision



Vision loss



Any other visual changes

1. Balversa™ Prescribing Information. April 2020.

2. Nicholson B, et al. *Surv Ophthalmol*. 2013;58(2)103–126.






3. Macular Society. Central Serous Retinopathy.

<https://www.macularsociety.org/central-serous-retinopathy> (Accessed 09 Nov 2020).

Why should you have regular eye examinations during erdafitinib treatment?¹

- Your oncologist may refer you for an eye examination before you start taking erdafitinib to check the health of your eyes.
- Throughout your erdafitinib treatment, you will be asked to have regular eye examinations.
- Regular eye examinations are still important even if you do not have any CSR symptoms.
 - Some patients with CSR may not experience any changes in vision, and CSR may only be detected upon eye examination.
- **Tell your oncologist immediately** if you experience blurred vision, loss of vision, or any other visual changes during your erdafitinib treatment.

What eye tests may be performed?¹

Amsler grid test  You will be asked to look at a grid to identify any changes in your vision.	Visual acuity  You will be asked to read from an eye chart to measure your vision over distances.	Optical coherence tomography  A camera-like device will take images of the back of your eye.	Slit lamp examination  The front of your eye will be examined using a microscope.	Fundoscopy  The back of your eye will be examined using a special lens.
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What happens if you develop CSR while taking erdafitinib?¹

If CSR is detected, your oncologist may stop your erdafitinib treatment for a period of time or adjust the dose.

Often no treatment is necessary for CSR: once erdafitinib has been stopped, the fluid behind the retina can be reabsorbed by the eye after several weeks or months.

- If sight has been affected, the majority of people regain most or all of their sight.

After erdafitinib treatment is restarted, it may be at a lower dose to help prevent CSR from returning.

If CSR does return or symptoms worsen, your erdafitinib treatment may be permanently stopped.

Patient Information Card

- You will be provided with a small information card explaining that you are currently taking erdafitinib and may be at risk of developing CSR.
- The intent of this card is to alert your eye care specialist or other healthcare provider of the necessary eye exams you require before or while being treated with erdafitinib, and actions to take if eye problems, such as CSR, are detected.
- You will need to show this card to your eye care specialist or other healthcare provider at every appointment.



If you have additional questions about CSR, please speak to your oncologist or eye care specialist.

- If you have any additional questions, please contact Janssen Medical Information
 - RA-MedInfoEmMarkets@ITS.JNJ.com
- **Adverse events reporting guidance:**
 - SFDA (National Pharmacovigilance center)
 - Email: npc.drug@sfd.gov.sa
 - Telephone: 19999
 - Fax: +966 11 2057662
 - Online: <http://ade.sfda.gov.sa>
- For full prescribing information, please refer to the data sheet or contact **Johnson & Johnson Middle East FZ-LLC (Riyadh)**
 - Address: Prince Muhammed Bin Abdulaziz Rd, Tower B, Level 30 , Olaya towers.
 - Office Tel 00966-11- 4339133
 - Postal address: P O Box 65305 Riyadh 11556, Saudi Arabia
- To report Adverse Events/Product Complaint or any Medical Information Inquiries, please contact us at Email: GCC-PV2@its.jnj.com
 - Hotline: 00966540015811