HCP Training Deck

Central Serous Retinopathy (CSR) : Recommendations for the diagnosis and management of CSR in context of treatment with Erdafitinib

Balversa™ (erdafitinib) 3, 4, 5 mg tablets

This risk minimization activity version 2 has been approved by the Saudi FDA July 2021

Janssen PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Welcome to this training deck!

This slide deck is designed to support healthcare professionals in the screening, diagnosis, evaluation, and management of patients who experience **central serous retinopathy (CSR)** while receiving **erdafitinib**.

This training deck will:

- Outline that erdafitinib can cause ocular toxicities.
- Recommend a baseline ophthalmologist visit takes place.
- Confirm that patient training on the Amsler grid test should be provided.
- Recommend that follow-up visits should take place to monitor visual changes.
- Outline the management of CSR-related ocular toxicities.

Balversa™ (erdafitinib) 3, 4, 5 mg tablets

Version 2 July 2021

Janssen PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Contents

Balversa™ (erdafitinib) 3, 4, 5 mg tablets

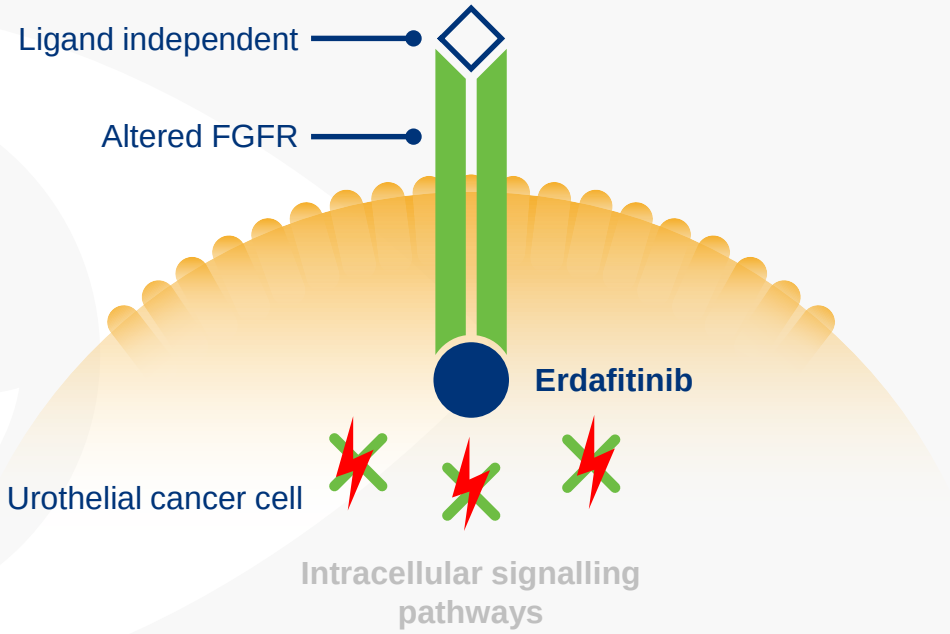
Click on these icons to navigate through the training deck at all times

Version 2 July 2021

Janssen PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Introducing erdafitinib[1]

- Erdafitinib is a tyrosine kinase inhibitor that binds to and inhibits enzymatic activity of **FGFR1, FGFR2, FGFR3 and FGFR4**.[1]
- It is used to treat adults with **locally advanced metastatic urothelial carcinoma.**
  - With susceptible **FGFR2 or FGFR3 genetic alterations.**
  - And who have progressed during or following at least one line of prior platinum-containing chemotherapy, including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.



FGFR, fibroblast growth factor receptors

Balversa™ (erdafitinib) 3, 4, 5 mg tablets

janssen PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Erdafitinib: safety information[1]

Since **erdafitinib** targets the **FGFR protein** and may affect other cells with this protein, it may cause side effects including:

mouth sores	feeling tired	change in kidney function	diarrhea
dry mouth	nails separate from the bed \ poor formation of the nail		change in liver function
low sodium levels	decreased appetite	change in sense of taste	constipation
anemia	dry skin	hair loss	dry/inflamed eyes
abdominal pain	nausea	muscle pain	

Eye problems are common with erdafitinib and include:

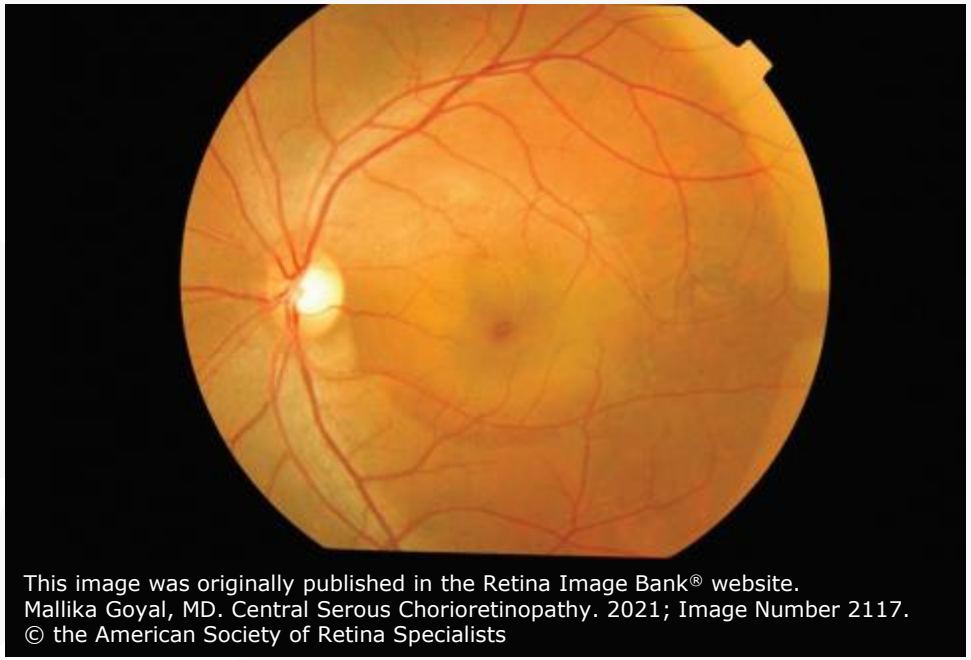
- dry or inflamed eyes
- inflamed cornea
- and disorders of the retina (i.e. CSR) that could cause visual field defect

Balversa™ (erdafitinib) 3, 4, 5 mg tablets

janssen PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Overview of central serous retinopathy (CSR)[2]

- In patients with **central serous retinopathy (CSR)**, fluid accumulates under the retina causing a serous (fluid-like) detachment of the retinal epithelium and vision loss.
- This condition most often occurs in young and middle-aged adults, and in men more commonly than women.
- **Symptoms include:** blurry central vision, which often occurs in one eye
  - However, these patients may display no symptoms, especially if the affected areas fall outside the macula.
- CSR may be detected and quantified with optical coherence tomography (OCT)
- Treatment is often not necessary since **most cases of CSR resolve without treatment** after several weeks or months
  - If retinal swelling persists for more than three or four months, or if an examination reveals early retinal degeneration, laser surgery or photodynamic therapy may be helpful.



This image was originally published in the Retina Image Bank® website. Mallika Goyal, MD. Central Serous Chorioretinopathy. 2021; Image Number 2117. © the American Society of Retina Specialists

Mechanism of action

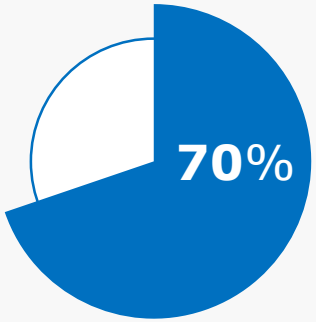
FGFR signalling is thought to be involved in the maintenance, protection, and repair of the retinal pigment epithelium for which inhibition could lead to **CSR**.

Balversa™ (erdafitinib) 3, 4, 5 mg tablets

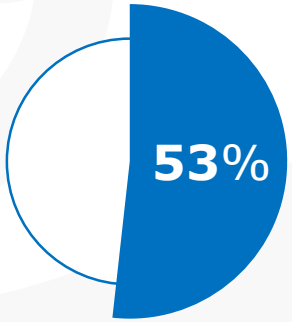
janssen PHARMACEUTICAL COMPANIES OF Johnson & Johnson

CSR has been reported in erdafitinib clinical studies[1]

- Ocular disorders, including **CSR**/retinal pigment epithelial detachment resulting in visual field defect, have been reported in patients receiving **erdafitinib** in clinical studies.
- In the Phase II BLC2001 study of patients with **locally advanced and unresectable or metastatic urothelial carcinoma and** prespecified **FGFR alterations**, **CSR** was observed in 25% of **erdafitinib**-treated patients
  - Median time to first onset was 50 days.



An abnormal Amsler grid test result was identified in **70%** of patients who developed CSR.



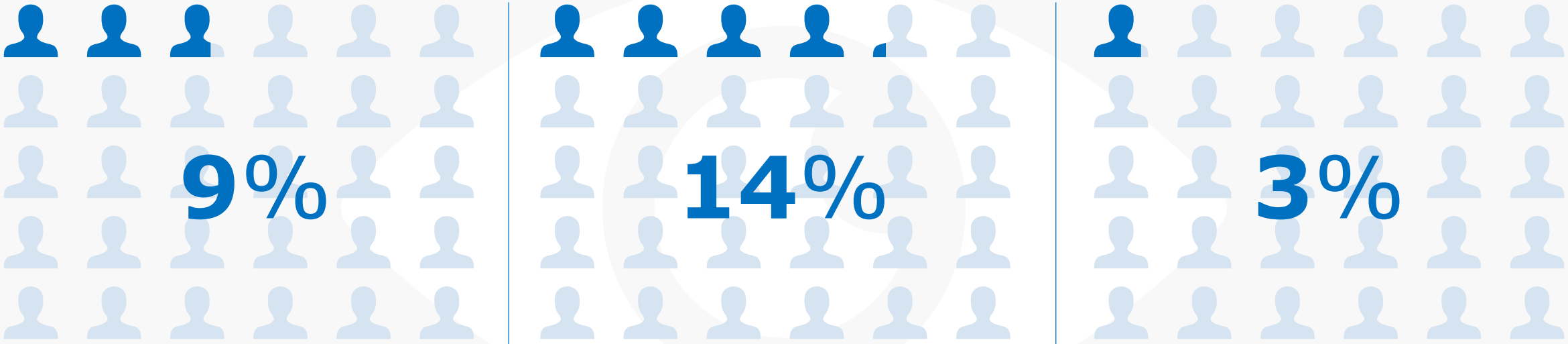
Ocular disorders other than **CSR** occurred in **53%** of patients, including **dry eye (20%)** and **blurred vision (17%)**.

Balversa™ (erdafitinib) 3, 4, 5 mg tablets

janssen PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Management of CSR in erdafitinib clinical studies[1]

In clinical studies, **CSR** was primarily managed by dose modification:



Balversa™ (erdafitinib) 3, 4, 5 mg tablets

Screening recommendations for CSR prior to and during erdafitinib[1]

Prior to initiating erdafitinib, a baseline ophthalmological exam is recommended and should include an Amsler grid test, fundoscopy, visual acuity, and an optical coherence tomography (OCT) if available.

Patients should be examined by an eye specialist every month thereafter; examinations should include performing an Amsler grid test.

Guidance should also be provided for patients to self-administer the Amsler grid test to detect visual abnormalities between physician visits.

Balversa™ (erdafitinib) 3, 4, 5 mg tablets

janssen PHARMACEUTICAL COMPANIES OF Johnson & Johnson

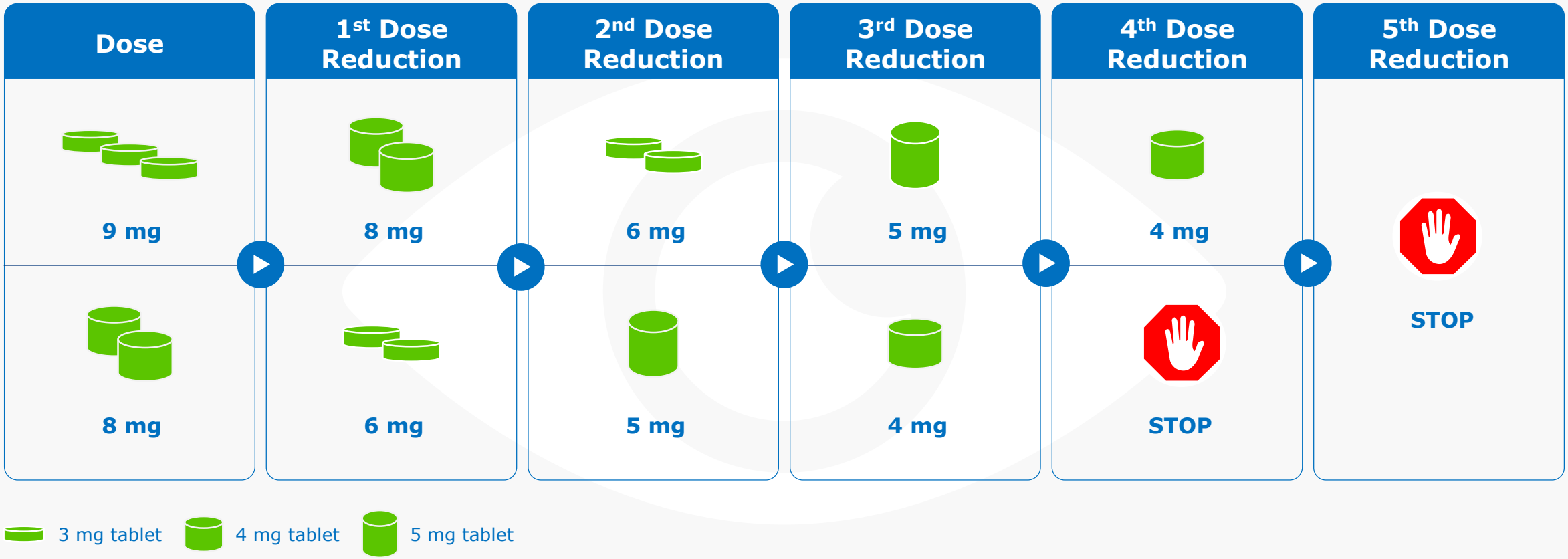
Management recommendations for CSR during erdafitinib[1]

Severity Grading	Erdafitinib Drug Management
Grade 1: Asymptomatic; clinical or diagnostic observations only	• Withhold until resolution • If resolves within 4 weeks, resume at the next lower dose level. Then, if no recurrence for a month, consider re-escalation • If stable for 2 consecutive eye exams but not resolved, resume at the next lower dose level
Grade 2: Visual acuity 20/40 or better or ≤3 lines of decreased vision from baseline	• Withhold until resolution • If resolves within 4 weeks, may resume at the next lower dose level
Grade 3: Visual acuity worse than 20/40 or >3 lines of decreased vision from baseline	• Withhold until resolution • If resolves within 4 weeks, may resume two dose levels lower • If recurs, consider permanent discontinuation
Grade 4: Visual acuity 20/200 or worse in affected eye	• Permanently discontinue

Balversa™ (erdafitinib) 3, 4, 5 mg tablets

janssen PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Erdafitinib dose reduction schedule[1]



Balversa™ (erdafitinib) 3, 4, 5 mg tablets

janssen PHARMACEUTICAL COMPANIES OF Johnson & Johnson

References

1. Balversa™ (erdafitinib) Prescribing Information (April 2019). https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/212018s000lbl.pdf (Accessed 12 Aug 2020).
2. Central Serous Chorioretinopathy. Retina Health Series. American Society of Retina Specialists. 2016; (312): 578-8760.

Contact information

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@sfda.gov.sa
Telephone: 19999
Fax: +966 11 2057662
Online: http://ade.sfda.gov.sa

For full prescribing information, please contact Johnson & Johnson Middle East FZ-LLC Branch (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

Contact information

في حال اي استفسارات علميه اضافيه الرجاء الاتصال بقسم المعلومات العلميه بجانسن على البريد الالكتروني:

RA-MedInfoEmMarkets@ITS.JNJ.com

للابلاغ عن الأعراض الجانبية:

هيئة الغذاء والدواء (المركز الوطني للتيقظ)

الإيميل : npc.drug@sfda.gov.sa

الخط المباشر: 19999

•فاكس: 00966112057662

الموقع : http://ade.sfda.gov.sa

للحصول على معلومات عن طريقة استخدام الدواء , يرجى الرجوع الى النشرة الداخلية او التواصل مع فرع شركة جونسون أند جونسون ميدل ايست (الرياض)

العنوان: شارع الأمير محمد بن عبدالعزيز، برج ب، الطابق30 أبراج العليا.

الهاتف: 00966114339133

ص.ب: 65305 الرياض 11566 ، السعودية

للإبلاغ عن الأعراض الجانبية و شكاوى عن المنتجات او اي

استفسارات طبية, يرجى التواصل بنا عبر:

الإيميل : GCC-PV2@its.jnj.com

الخط المباشر: 00966540015811

Balversa™ (erdafitinib) 3, 4, 5 mg tablets

janssen PHARMACEUTICAL COMPANIES OF Johnson&Johnson