sanofi

Direct Healthcare Professional Communication

07-Feb-2023

Clomifene citrate (Clomid): Visual disorders associated in some cases with reversible or permanent/irreversible, partial or total, visual impairment (blindness).

Dear Healthcare professional,

SANOFI Saudi Arabia in agreement with the Saudi Food and Drug Authority (SFDA) would like to inform you of the following:

Summary

- **Visual disorders such as blurred vision, reduced visual acuity, phosphenes, and scintillating scotomas (spots or flashes) are known risks associated with clomifene.**
- **New adverse reactions and new aspects of the following adverse reactions have been reported during postmarketing experience: optic neuritis, optic ischaemic neuropathy, central retinal vein occlusion, retinal detachment and vitreous detachment.**
- **These new adverse reactions were associated in some cases with reversible or permanent/irreversible, partial or total visual impairment (blindness), including after clomifene discontinuation.**
- **These visual disorders have been observed especially with increased dosage or duration of therapy.**
- **At the initiation of the treatment, the patient should be instructed to stop clomifene immediately and inform the physician, whenever any unusual visual symptom occurs.**
- **In patients experiencing visual disorders, a complete ophthalmological examination is required and the treatment should be permanently discontinued if no other cause of visual disorder is determined.**
- **Clomifene must not be used in case of history of visual disorders associated with clomifene use (previous or current treatment course).**

Background on the safety concern

Clomid 50 mg Tablets (Clomifene Citrate BP) is indicated for the treatment of ovulatory failure in women desiring pregnancy.

Clomid 50 mg Tablets is indicated only for patients in whom ovulatory dysfunction is demonstrated.

Other causes of infertility must be excluded or adequately treated before giving Clomid 50 mg Tablets.

Clomifene citrate is already known to induce ocular and vision disorders. The exact mechanism of visual disorders is not elucidated.

Cases of optic neuritis, optic ischemic neuropathy, central retinal vein occlusion, retinal detachment, and vitreous detachment have been reported during post-marketing experience (spontaneous reports and literature) with a frequency "rare" in the case of optic neuritis and a frequency "not known" for the other adverse reactions.

These adverse reactions and their associated symptoms "diplopia, eye pain and accommodation disorders" have been reported as possibly related to the use of clomifene, and sometimes associated with reversible or permanent/irreversible, partial or total loss of vision (blindness) including after clomifene discontinuation.

The analysis of post marketing cases has not identified risk factors or specific patho-mechanism, despite in some cases, longer duration and higher dosage than recommended. Therefore, occurrence, severity and potential consequences of visual disturbances cannot be anticipated for each case.

Patients should be informed of the vision disorders' symptoms and the potential risk of visual loss.

Patients should be instructed to stop clomifene immediately and inform their physician whenever any unusual visual symptoms occur.

In such cases, a complete ophthalmological examination is required, and the treatment should be permanently discontinued, if no other cause of visual disorders is determined.

Clomifene must not be used in case of history of visual disorders associated with clomifene use (previous or current treatment course).

The product information has been updated to contain instructions/recommendations about the risk of visual disorders associated in some cases with reversible or permanent/irreversible, partial or total, visual impairment (blindness).

Call for reporting

Reporting suspected adverse reactions after authorization 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 to National Pharmacovigilance and Drug Safety Center in SFDA.

Website: https://ade.sfda.gov.sa/

E-mail: npc.drug@sfda.gov.sa

Phone: 1999

Fax: +966-11-2057662

Company contact point

For SANOFI Saudi Arabia Pharmacovigilance Center please contact us in the below contact information.

Email: Ksa_pharmacovigilance@sanofi.com

Mobile: + 966-54-428-4797

For Medical Information enquiries, please contact:

Phone: +966 12 669 3318 | Email: ksa.medicalinformation@sanofi.com

Annexes:

1- Judith Marcin, M.D., Kimberly Holland, June 2, 2017, What Causes Diplopia (Double Vision), Diplopia (Double Vision): Monocular and Binocular Causes and Treatment.
2- Ann Marie Griff, Kimberly Holland, November 25, 2019, What You Need to Know About Eye Pain, Eye Pain: Causes, Treatments, and Prevention.
3- Dr. Russel Lozorus, July 4, 2021, Accommodative dysfunction is an eye focusing difficulty that can impact a child's school grades, Optometrists Network.
4- Mulugeta Russom[1]*, Bastola Pradeep[2], Mehari Zeregabr[1], Kahsay Fessehatzion[3] and Natnael Araya[4], 2017, Blindness and retinal disorder associated with clomifene citrate: Cases series assessment, Clinical and Medical Investigations.
5- https://www.cdc.gov/visionhealth/basics/ced/index.html.
6- https://www.who.int/news-room/fact-sheets/detail/blindness-and-visual-impairment.

Best regards,

Mossab Shafy

Country Safety Head & Local QPPV

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