



Direct Healthcare Professional Communication

Oct 2023

Clomiphene: risk of serious visual disturbances (blindness)

Dear Healthcare Professional,

The General Administration for Pharmaceutical Vigilance of the Central Administration for Pharmaceutical Care at The Egyptian Drug Authority would like to inform you of the following **risk of serious visual disturbances**:

Summary:

- Visual disturbances such as blurred vision, reduced visual acuity, phosphenes, and scotomas sparkles (spots or flashes) are known risks associated with clomiphene.
- Recently new visual adverse effects have been reported with the use of clomiphene: optic neuritis, ischemic optic neuropathy, central retinal vein occlusion, retinal detachment and vitreous detachment.
- These side effects have in some cases led to reversible or irreversible, partial or total visual impairment (blindness), including after discontinuation of clomiphene, particularly when increasing the dosage or duration of treatment.
- At the start of treatment, the patient should be warned of the risk and that, if unusual visual disturbances appear, she should immediately stop her treatment with clomiphene and inform her doctor.
- In case of visual disturbances, a complete ophthalmological examination is necessary; If no cause other than clomiphene is identified for visual disturbance, clomiphene treatment should be permanently discontinued.
- History of visual disturbances associated with the use of clomiphene (previous treatment cycle or current) constitute a contraindication to any further treatment.

Further information on the safety concern and the recommendations

The indications for (clomiphene citrate) are as follows:

- Treatment of infertility by normoprolactinemic anovulation and dysovulation of high functional origin:
 - infertility by anovulation
 - infertility by dysovulation:
 - "inadequate corpus luteum",
 - short luteal phase,





- polycystic ovary syndrome;
- Test for both diagnostic and therapeutic purposes:
 - in certain amenorrhea of hypothalamic-pituitary origin,
 - in lasting amenorrhea following oral contraception (after checking that the rate of plasma prolactin is normal).
 - Induction of ovulation in the context of medically assisted procreation (intrauterine insemination, IVF).

Clomiphene citrate is already known to induce eye and vision disorders. The exact mechanism of visual disturbances is not fully understood.

Cases of optic neuritis, ischemic optic neuropathy, central retinal vein occlusion, retinal detachment and vitreous detachment have been reported since the marketing of clomiphene (statements reports and analysis of the literature) with a “rare” frequency in the case of optic neuritis and an “undetermined” frequency for the other visual adverse effects.

These adverse reactions and their associated symptoms “diplopia, ocular pain and disturbance of accommodation” have been reported as possibly related to the use of clomiphene, and sometimes associated with reversible or permanent, partial or total loss of vision (blindness)., including after discontinuation of treatment.

Analysis of reported cases did not identify risk factors or specific mechanism, despite longer duration and higher dosage than recommended in some cases. Therefore, the occurrence, severity and potential consequences of visual disturbances cannot be predicted for each case.

Reference:

ANSM: <https://ansm.sante.fr/informations-de-securite/clomid-50-mg-comprime-risque-de-troubles-visuels-graves-cecite>

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: General Administration for Pharmaceutical Vigilance

Email: pv.followup@edaegypt.gov.eg

Online reporting: <https://primaryreporting.who-umc.org/EG>

QR Code:



Hotline: 15301



The Arab Republic of Egypt
Egyptian Drug Authority

Central Administration for
Pharmaceutical Care

General Administration for
Pharmaceutical Vigilance



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