



Direct Healthcare Professional Communication

Oct 2024

(isotretinoin) - Reminder of the existing restrictions on Preventing exposure during pregnancy

Dear Healthcare Professional,

The General Administration for Pharmaceutical Vigilance of the Central Administration for Pharmaceutical Care at The Egyptian Drug Authority would like to Remind you **restrictions on Preventing exposure during pregnancy.**

Summary:

- Oral retinoids are highly teratogenic and their use is therefore contraindicated during pregnancy.
 - Oral retinoids are also contraindicated in women of childbearing potential unless all conditions of the pregnancy prevention programme (PPP) are met.
 - Recent studies conducted in some European countries have shown that the PPP measures are not being adequately complied with.
 - **Doctors are therefore reminded of the following:**
 - The approved indications must be strictly observed when prescribing oral retinoids (example: isotretinoin: severe acne that does not respond to adequate standard therapy).
 - Pregnancy must be ruled out before treatment is started. Women of childbearing age must therefore perform a pregnancy test under medical supervision shortly (within the last 3 days) before the first prescription. In addition, these patients must undergo monthly pregnancy tests supervised by a doctor during treatment. After treatment, a medically supervised pregnancy test must be performed one month after stopping isotretinoin or alitretinoin, and after stopping acitretin, regular medically supervised pregnancy tests must be performed at 1-3 monthly intervals for a period of 3 years.
 - Women of childbearing age must use effective contraception in accordance with PPP without interruption for at least 1 month before starting therapy and throughout the entire treatment. Under certain conditions, contraceptives are reimbursable. This should be clarified beforehand with the responsible health insurance company. After therapy, effective contraception must continue to be used in accordance with PPP: for isotretinoin and alitretinoin for a period of one month after cessation of treatment and for acitretin for a period of 3 years after cessation of treatment.
 - This applies to all women of childbearing potential, including sexually inactive patients and women with amenorrhea
-



Background

Oral retinoids are used to treat severe forms of acne, severe chronic hand eczema that does not respond to corticoids, severe forms of psoriasis and keratinization disorders.

The oral retinoids acitretin, alitretinoin and isotretinoin are highly teratogenic. They are strictly contraindicated in pregnant women. They may only be used in all women of childbearing age if the Pregnancy Prevention Programme (PPP) is observed .

The results show that while taking oral retinoids, the use of contraceptive measures and pregnancy testing is still low. Pregnancies continue to occur in women treated with oral retinoids, most of which result in termination of pregnancy.

The survey “Prescriber and Patient/Caregiver Survey: Effectiveness measures to investigate awareness, knowledge, and adherence to the Risk Minimization Measures (RMMs) of the Pregnancy Prevention Program (PPP) for oral retinoids (acitretin, alitretinoin, and isotretinoin)” was conducted to assess physicians and patients/caregivers’ awareness, knowledge, and adherence to the PPP.

The survey results show that physicians and patients/their caregivers are aware of the RMMs of the PPP and that oral retinoids are teratogenic, should not be taken during pregnancy, and that contraceptive measures and regular pregnancy testing are necessary. However, physician-supervised pregnancy testing was not performed sufficiently and effective contraception during treatment and after treatment was not ensured.

Reference:

BfArM:

<https://www.bfarm.de/SharedDocs/Risikoinformationen/Pharmakovigilanz/EN/RHB/2024/rhb-retinoide-oral.html>

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

