

Direct Healthcare Professional Communication

Date: 02/Feb/2026

Isotretinoin (Roaccutane®) – Important Safety Information on Psychiatric and Sexual Disorders

Dear Healthcare Professional,

In agreement with the Saudi Food and Drug Authority (SFDA), Cheplapharm Schweiz GmbH would like to inform you about important new safety information regarding psychiatric disorders and sexual disorders associated with isotretinoin (Roaccutane®).

Roaccutane® is a retinoid indicated for the treatment of severe forms of acne (such as nodular or conglobate acne or acne at risk of permanent scarring) resistant to adequate courses of standard therapy with systemic anti-bacterials and topical therapy.

Summary

- Cases of depression, depression aggravated, anxiety, aggressive tendencies, mood alterations, psychotic symptoms, and very rarely, suicidal ideation, suicide attempts and suicide have been reported in patients treated with isotretinoin.
- Cases of sexual dysfunction including erectile dysfunction and decreased libido, gynecomastia and vulvovaginal dryness have also been reported.
- Recommendations for prescribers:
 - Assess patients' mental health status and family history prior to initiating isotretinoin.
 - Exercise particular caution in patients with a history of depression.

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- Monitor all patients for psychiatric symptoms throughout treatment during regular visits.
- If psychiatric symptoms occur or worsen, discontinue isotretinoin promptly and refer the patient for psychiatric evaluation.
- Assess patients for signs or symptoms of sexual dysfunction before starting therapy and monitor during treatment.
- If symptoms of sexual dysfunction occur, specialist evaluation may be required. This DHPC should be used in conjunction with the approved patient reminder card and physician checklist.
- Discontinuation of isotretinoin may not always resolve psychiatric or sexual disorders.
- Prescribers should ensure patients and caregivers are informed about early warning signs.

Further information on the safety concerns and recommendations

Psychiatric disorders

- Reports of depression, depression aggravated, aggressive tendencies, anxiety, mood alterations, and very rarely, suicide, suicide attempt, suicidal ideation, psychotic disorder and abnormal behaviour have been received during isotretinoin therapy.
- The mechanism behind these adverse reactions is not established.
- Prior to starting isotretinoin, patients should undergo an assessment of mental health and family psychiatric history.
- Careful monitoring is required throughout treatment.
- If psychiatric symptoms develop, treatment should be discontinued and the patient referred to a psychiatrist or mental health specialist.

Sexual disorders

- Post-marketing reports describe sexual dysfunction including erectile dysfunction and decreased libido, gynecomastia and vulvovaginal dryness in patients treated with isotretinoin.

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- These events may persist after discontinuation, and in such cases, further specialist evaluation is recommended.
- Prescribers should discuss potential risks with patients, evaluate any pre-existing sexual dysfunction prior to treatment, and monitor for new symptoms during treatment.

Please forward this information to relevant staff members in your organization dealing with the product.

Call for reporting

Healthcare professionals are encouraged to report any suspected adverse drug reactions (ADRs) associated with isotretinoin (Roaccutane®) through the following channels:

**The National Pharmacovigilance
Center (NPC) at the Saudi Food and
Drug Authority (SFDA)**

Abdulrehman Algosaibi G.T.C

SFDA Call Center: 19999

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

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

SFDA Reporting Web-Page

Email: safety@aralgosaibico.com

Tel: +966 11 4793000

Mobile: +966 58 016 0683

*AlGosaibi Adverse Event (AE)
Electronic Report*



Yours sincerely,

Hamza Al-Sayegh
Local Qualified Person Responsible for Pharmacovigilance (QPPV)
Abdulrehman Algosaihi G.T.C
representing CHEPLAPHARM Schweiz GmbH

References

National Guideline Alliance (UK). Information and support: Acne vulgaris: management: Evidence review A. London: National Institute for Health and Care Excellence (NICE); 2021 Jun. (NICE Guideline, No. 198.)

Paljarvi T, McPherson T, Luciano S, Herttua K, Fazel S. Isotretinoin and adverse neuropsychiatric outcomes: retrospective cohort study using routine data. Br J Dermatol. 2022 Jul;187(1):64-72.

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