



Direct Healthcare Professional Communication

Isotretinoin– update on neuropsychiatric disorders

Dear Healthcare Professional,

Roche Products Saudi Arabia in agreement with the Saudi Food and Drug Authority would like to inform you of the following:

Summary

Neuropsychiatric disorders

- Cases of depression, depression-aggravated anxiety, and mood alterations have been reported rarely in patients taking oral retinoids.
- Advise patients taking oral retinoids that they may experience changes in their mood and/or behavior and that they and their families should be alert to this and should speak to their doctor if this occurs.
- Monitor all patients treated with oral retinoids for signs and symptoms of depression and refer for appropriate treatment, if necessary. Special care should be taken in patients with history of depression.

Background on the safety concern

- Isotretinoin is used in 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.
- Following a recent in-depth review of all relevant data, the Pharmacovigilance Risk Assessment Committee has strengthened information provided to patients and healthcare professionals on neuropsychiatric disorder.
- Roche Products Saudi Arabia in agreement with the Saudi Food and Drug Authority to inform the prescribing HCPS with these updates

Neuropsychiatric disorders

Depression, depression-aggravated anxiety, and mood alterations have been reported in patients treated with oral retinoids. The available evidence from published literature and individual case reports shows conflicting study results, and the published studies suffer from a number of limitations. Therefore, it has not been possible to identify a clear increase in risk of psychiatric disorders in people who take oral retinoids compared to those that do not. Furthermore, it is recognized that patients with severe skin disorders are themselves at an increased risk of psychiatric disorders. It is recommended that patients who are taking oral retinoids are advised of the possibility that they may experience changes in their mood and behavior and that they should speak to their doctor if this happens. Any patient who shows signs of depression should be referred for appropriate treatment, as necessary. Special attention should be given to patients treated with oral retinoids with a history of depression, and all patients should be monitored for signs of depression.

11-September-2019



Call for reporting

Roche Products Saudi Arabia would like to remind physicians about the importance of reporting suspected adverse reactions following the use of Roaccutane, in order to facilitate continuous monitoring of the benefit/risk balance of the product. Healthcare professionals are asked to report any suspected adverse reactions via the national spontaneous reporting system:

The National Pharmacovigilance Centre (NPC)

Land Line: 19999.

Website: [https://:ade.sfda.gov.sa](https://ade.sfda.gov.sa)

Email: npc.drug@sfda.gov.sa

Fax: +96612057662.

Company contact point

Should you have any questions regarding the use of Roaccutane, please feel free to contact us at:

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Local Safety Responsible: Hassan.linjawi@roche.com

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Yours sincerely,

A handwritten signature in black ink, appearing to be "Hassan Linjawi", with the date "11. Sep. 2019" written below it.



**Hassan Linjawi, QPPV.
Roche Products Saudi Arabia**