



Hoffmann La-Roche

Saudi Import Company

Najoud Centre, Gate A, 1<sup>st</sup> Floor

Prince: Mohamed Bin Abdulaziz St.

Date: 17/03/2014

**Reminder: Pregnancy Prevention Program and Safety Information about Roaccutane**

Dear Pharmacist,

Hoffmann-La Roche would like to remind you about very important information to be always considered when dispensing Roaccutane® (active ingredient: isotretinoin) to the patients.

Roaccutane® is a retinoid indicated for the treatment of severe forms of acne (nodular or conglobate acne, or acne at risk of permanent scarring) and acne which has failed to respond to standard therapies with systemic antibacterials and topical therapies.

Roaccutane® is **teratogenic** and therefore special benefit-risk considerations and precautions are required when women of childbearing potential are being treated. Therefore the risk of Roaccutane® therapy must be weighed against the expected benefit in light of all possible side effects.

If a female patient should become pregnant before, during or within a month after end of treatment with Roaccutane, there is a high risk of severe fetal malformations, mainly involving the central nervous system, heart and major blood vessels e.g. hydrocephalus, microcephaly, external ear deformities (micropinna, small or absent external auditory canals), microphthalmia, abnormalities of the thymus and parathyroid glands and cerebellar malformations.

If a pregnancy occurs, doctor and patient should jointly clarify whether a continuation of the pregnancy is advisable.

Appropriate medical support and monitoring measures should be readily available during Roaccutane® therapy. It is mandatory to advise patients about benefits and risks of a Roaccutane treatment, to immediately discontinue the medication if a pregnancy should occur during the treatment with Roaccutane and to immediately inform the treating dermatologist directly.

To aid prescribing physicians in preventing fetal exposure to Roaccutane, and to reinforce the warnings to avoid pregnancy, all female patients of childbearing age must be given the following documents that will be distributed by Saudi Import Company (BANAJA) the official distributor of Hoffmann La-Roche in Saudi Arabia.

- Medication guide, including Medical Consent form.
- Contraceptive Methods.

The contraception brochure and consent form must be handed to all female patients before the start of treatment. Female patient's not already practicing reliable contraception must receive the documents no later than one month before commencing oral Roaccutane, i.e. at the required starting time for reliable contraception. Prescribing Physicians should insure that appropriate contraception control is being followed (two different types of birth control must be used).

#### **FURTHER PRECAUTIONS & INSTRUCTIONS FOR FEMALE PATIENTS**

- Roaccutane is contraindicated in women of childbearing potential unless the female patient meets all the conditions of the Pregnancy Prevention Program.
- The information on the Pregnancy Prevention Program should be given to patients orally and as a brochure and sections should be explained to female patients as needed.
- Microdosed progesterone preparations (minipills) may be an inadequate method of contraception during Roaccutane® therapy.

The information provided in this letter has been agreed with the Saudi Food & Drug Authority.

#### **CALL FOR REPORTING:**

Roche monitors the safety of its products through established reporting mechanisms and notifies Saudi Food and Drug Authority of any serious adverse events.

You can assist us in monitoring the safety of Roaccutane by reporting adverse reactions to the following contact details.

Phone number +966 12 2847198 Ext 221  
Fax number +966 12 2847190 Ext 131.  
Email: [Jeddah.drug\\_safety@roche.com](mailto:Jeddah.drug_safety@roche.com)

Or

The National Pharmacovigilance & Drug Safety Center (NPC)  
Saudi Food & Drug Authority (SFDA)  
Toll free number: 8002490000  
Fax. +966-11-2057662  
Email: [Npc.drug@sfda.gov.sa](mailto:Npc.drug@sfda.gov.sa)  
Online: <https://ade.sfda.gov.sa/>

Should you have any questions or require additional information regarding the use of Roaccutane® please contact:

F.Hoffmann La-Roche  
Najoud Centre, Gate A, 1st Floor  
Prince Mohamed Bin Abdulaziz St.  
Phone: + 966 12 2847190 Ext.221  
Jeddah, SA

Sincerely,

Nasser Al-Rajhi  
Scientific Office Director

17 March 2014



Hazem Dajani  
Local safety Responsible

H. Dajani  
17/3/2014

Tamer Elmahallawy  
Medical director

Tamer  
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