



**MINISTRY OF HEALTH  
PHARMACY AND POISONS BOARD**

**SAFETY COMMUNICATION FOR HEALTHCARE PROVIDERS: Additional  
RISK MINIMIZATION MEASURES (aRMM) FOR ROACUTANE  
(ISOTRETINOIN)**

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**Introduction**

Roaccutane (Isotretinoin) is a retinoid used to manage severe forms of acne, including nodular or conglobate acne or acne, and cases at risk of permanent scarring. It is prescribed when standard treatments, such as systemic antibiotics and topical therapies, have proven ineffective. In the Kenyan market, **Roaccutane is available as soft gelatin capsules in 10 mg and 20 mg strengths.**

Isotretinoin offers significant benefits, but is also associated with risks of teratogenicity and congenital malformations in patients undergoing treatment. Although the exact mechanism of isotretinoin's teratogenic effects is not fully understood, it is believed that its metabolism into all-trans-retinoic acid and its interaction with various retinoid receptors play crucial roles in normal embryonic development. Disruptions in this process can result in birth defects. Due to this significant risk, pregnancy is considered an absolute contraindication for isotretinoin treatment. Women of childbearing potential must use effective contraception during treatment and for up to one month after stopping the medication.

**To further minimize these risks, marketing authorization holders for Isotretinoin are advised to develop additional risk minimization measures to ensure patient safety.**

The Pharmacy and Poisons Board, in agreement with Roche, would like to provide healthcare professionals with important information regarding additional Risk Minimization Measures (aRMM) designed to reduce the risks associated with prescribing and dispensing Roaccutane to pregnant women. The aRMM includes a physician checklist, a pharmacist checklist, and a patient card.

i. Physician Checklist

The physician's checklist must be completed for all female patients before prescribing Roaccutane. This checklist includes a set of questions that the patient

needs to answer in order to assess the potential for pregnancy prior to prescribing Roaccutane. The aim of the checklist is to:

- *Support discussions with patients;*
- *Present the key principles of the Pregnancy Prevention Programs;*
- *Record that those discussions have taken place.*

If the answer to any question in the checklist is **NO**, Roaccutane should **NOT** be prescribed.

ii. Pharmacist Checklist

The pharmacist checklist must be completed for all the female patients prescribed Roaccutane before dispensing the medication. The checklist provides guidance to pharmacists and other practitioners responsible for dispensing the product. The checklist also outlines the information to be provided to the patient during patient counselling sessions.

The aim of the pharmacist checklist is to;

- *Support pharmacist assessment of the Pregnancy Prevention Pregnancy obligations;*
- *Instruct the patient not to share medicine with others, to return unused medicine, and not to donate blood.*

The pharmacist should only dispense Roaccutane if **ALL** the checkboxes on the checklist are marked.

iii. Patient Card

All patients who are prescribed and dispensed Roaccutane shall be issued with a patient card. The card will indicate the number of hospital visits and the pregnancy test results during those visits. The aim of the patient card is to;

- *Support discussion with Health Care Provider;*
- *Present the key principles of the Pregnancy Prevention Program;*
- *Provide an opportunity for the patient to record doctor's visits, pregnancy test results, and contraception methods by means of an appointment table (inclusion of an appointment table in the Patient Reminder card is an optional measure);*
- *Act as a reminder and support discussions at the dispensing level.*

We encourage the reporting adverse events to the Board through the following channels:

For healthcare professionals:

- Complete and submit the report online at <https://pv.pharmacyboardkenya.org/>
- Submit the report through the MPvERS mobile application (available on the Play Store and App Store)
- Fill out the paper-based form available on the website (<https://web.pharmacyboardkenya.org/pharmacovigilance/> and send it to [pv@ppb.go.ke](mailto:pv@ppb.go.ke)

For the public:

- Dial USSD code \*271#
- Email: [pv@ppb.go.ke](mailto:pv@ppb.go.ke)
- Call: 0795 743 040

You may also report adverse events directly to Roche at [intake.sr-east-africa@roche.com](mailto:intake.sr-east-africa@roche.com)

The Pharmacy and Poisons Board sincerely thanks healthcare providers and the public for their continued efforts in ensuring the safe use of medicines.

For further information, please contact us at 0795 743 040 or via email at [pv@ppb.go.ke](mailto:pv@ppb.go.ke). Alternatively, you may reach Roche by email at [nairobi.medinfo@roche.com](mailto:nairobi.medinfo@roche.com) or by phone at +254 20 2715723.



**CHIEF EXECUTIVE OFFICER**  
**25<sup>th</sup> March, 2025**