

Challenges in Minimizing Risks with Oral Retinoids: An Analysis of Pharmacists' Adherence to Educational Materials

Kristina Angelova¹, Lília Leonardo¹, Ana Marreiros^{2,3}, João Paulo Fernandes⁴, Márcia Silva⁴, Margarida Espírito-Santo^{1,3,5*}

¹ Unidade de Farmacovigilância do Algarve e Baixo Alentejo (UFALBA), Faro, Portugal
² Faculdade de Medicina e Ciências Biomédicas da Universidade do Algarve, Faro, Portugal
³ Algarve Biomedical Center Research Institute (ABC-Ri), Faro, Portugal
⁴ INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.
⁵ Escola Superior de Saúde da Universidade do Algarve, Faro, Portugal

* E-mail: ufalba@abcmmedic.pt

1. INTRODUCTION

Oral retinoids (ORs), acitretin and isotretinoin, are medications for treating various dermatological conditions such as severe forms of psoriasis and acne but pose a risk of birth defects if used during pregnancy [1-3].

To mitigate these risks, a Pregnancy Prevention Program (PPP) was established, incorporating educational materials (EMs), as an essential tool for healthcare professionals, such as physicians and pharmacists [4]. However, previous studies indicate gaps in adherence to the PPP, across diverse countries, potentially compromising patient safety.



2. OBJECTIVES

The **primary objective** of this research was to evaluate the **effectiveness of EMs among community pharmacists** in mainland Portugal.

The **secondary objectives** were:

- To assess pharmacists **knowledge** of the risks and safety measures associated with the use of ORs;
- To assess **compliance** with the safety measures established in the EMs of the ORs;
- To assess the **accessibility** of EMs on ORs for pharmacists.

3. METHODOLOGY

Study Design	Cross-sectional observational study
Data collection	Data was obtained through questionnaires, completed from September 2023 to May 2024; Questionnaires were electronic, self-administered
Participants	Pharmacists
Inclusion criteria	❖ Pharmacists practicing in Community Pharmacy AND ❖ Having dispensed ORs within the past 5 years
Exclusion criteria	Those who might have conflicts of interest with the study (i.e., employees or service providers to regulatory agencies and/or pharmaceutical companies)

5. CONCLUSIONS

Pharmacists' adherence to the PPP and the proper use of **EMs are essential** to ensure the safety of patients using ORs.

It is recommended to implement measures to improve the dissemination, accessibility, and effectiveness of EMs, as well as to enhance pharmacist training.

Exploring alternative channels for the delivery of EMs could offer a promising approach to bridge the communication gap with patients.

Collaboration between pharmacists, health authorities, and the pharmaceutical industry is essential to ensure the safe and effective use of ORs.

4. RESULTS



Participants

67 pharmacists, working in community pharmacies

- Mean age of 38.4±11.2 years
- Predominantly female (92.5%; n=61)
- Practicing for ≥ 10 years (61.2%; n=41)

Dispensed Oral Retinoids (ORs)



- **Isotretinoin** was the most frequently dispensed OR (74.6%)
- Mostly prescribed for patients within their childbearing years (13-49 years; 98.5%).



Knowledge

Risks associated to ORs:

- Despite an adequate knowledge of OR risks among pharmacists, significant gaps were observed in the receipt and use of EMs.

Safety measures associated to the use of ORs:

- Nearly half of the pharmacists (52.2%; n=35) reported having no knowledge of any EMs related to ORs.
- Among those who were aware of such materials, the majority (78.1%; n=25) accessed the information through INFARMED's website.



Compliance with the safety measures

- 32.9% (n=22) reported providing an EM designed as "Patient Alert Card" when dispensing ORs
- 43.3% (n=29) reported delivering the patient information leaflet, which is not an EM, and must always be available inside the medication packaging.



Accessibility to EMs by pharmacists

- The preferred route by which pharmacists indicated they would like to receive EMs was e-mail (71.6%; n=48).
- When dispensing ORs, 12% (n=8) of pharmacists indicated using the "Guide for Pharmacists; Checklist – Guidance for dispensing ORs".

REFERÊNCIAS

1. Nast A, Dréno B, Bettoli V, Bukvic Mokos Z, Degitz K, Dressler C, et al. European evidence-based (S3) guideline for the treatment of acne - update 2016 - short version. J Eur Acad Dermatol Venereol. 2016;30(8):1261-8.
2. List of medicinal products under additional monitoring. Amsterdam: European Medicines Agency (EMA); 2023.
3. Manso G, Neira F, Ortega S, Martín Arias LH, Sainz M, Salgueiro E. Medicines under additional monitoring in the European Union. Farm Hosp. 2019;43(1):19-23.
4. Updated measures for pregnancy prevention during retinoid use. London: European Medicines Agency (EMA); 2018.