07 May 2026

Adalain (Adapalene + Benzoyl Peroxide 0.1% + 2.5% and 0.3% + 2.5% topical gel): Teratogenic risk and contraindication during pregnancy and in women planning pregnancy

Dear Healthcare Professional,

The marketing authorisation holder, Aristo Pharma GmbH in agreement with Italian Medicines Agency (AIFA), would like to inform you of the following:

Summary

- **Oral retinoids are highly teratogenic and must not be used during pregnancy.**
- **Topical retinoids, such as adapalene, are also contraindicated in pregnant women and in women planning a pregnancy as a precaution.**

Background on the safety concern

Adapalene is a retinoid for topical use indicated in the cutaneous treatment of acne vulgaris when comedones, papules, and pustules are present.

Oral retinoids are highly teratogenic. Following a recent in-depth review of all relevant data, the Pharmacovigilance Risk Assessment Committee strengthened information provided to patients and healthcare professionals on teratogenicity.

The data show that systemic exposure is negligible following topical application and these products are unlikely to result in adverse foetal outcomes. However, it is also recognised that humans are amongst the most sensitive species with respect to retinoid toxicity. On this basis, it was considered that a precautionary approach is advisable and that use of topical retinoids is contraindicated during pregnancy and in women planning a pregnancy.

Recommendations for healthcare professionals

- Do not prescribe or recommend the use of adapalene to patients who are pregnant or who intend to plan a pregnancy.
- Inform women of childbearing potential about the teratogenic risk and the contraindication for use during pregnancy.
- Immediately discontinue treatment if pregnancy is confirmed or suspected.

Call for reporting

AIFA reminds all healthcare professionals of the importance of reporting suspected adverse reactions, as this is a fundamental tool for confirming a favorable benefit–risk balance of medicines under real-life conditions of use.

Reports of suspected adverse reactions can be submitted

- *by completing the reporting form and sending it by e-mail to the Pharmacovigilance Officer of one's own institution (https://www.aifa.gov.it/responsabili-farmacovigilanza) or to the company that holds the Marketing Authorisation (MA) for the medicinal product suspected of having caused the adverse reaction,*
- *or directly online on the AIFA website (https://servizionline.aifa.gov.it/schedasegnalazioni/#/).*

This DHPC is also published on the AIFA website (https://www.aifa.gov.it/), where regular consultation is recommended to ensure optimal professional knowledge and service to citizens.