

Isotretinoin and the risk of erythema multiforme

Final SPC and PL wording agreed by the PhVWP in March 2010

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SUMMARY OF PRODUCT CHARACTERISTICS

Section 4.8 for all isotretinoin products

<i>Skin and subcutaneous tissues disorders:</i>	
Very common ($\geq 1/10$)	Cheilitis, dermatitis, dry skin, localised exfoliation, pruritus, rash erythematous, skin fragility (risk of frictional trauma)
Rare ($\geq 1/10\ 000, < 1/1000$)	Alopecia
Very Rare ($\leq 1/10\ 000$)	Acne fulminans, acne aggravated (acne flare), erythema (facial), exanthema, hair disorders, hirsutism, nail dystrophy, paronychia, photosensitivity reaction, pyogenic granuloma, skin hyperpigmentation, sweating increased
Frequency Unknown	Erythema multiforme

PACKAGE LEAFLET

Serious skin rash (erythema multiforme) appearing initially as circular patches often with a central blister usually on arms and hands or legs and feet but can affect any part of the body. If this rash develops, stop taking Roaccutane and contact your doctor.