

Isotretinoin and the risk of erythema multiforme

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

Doc. Ref.: CMDh/PhVWP/021/2010 Rev 1
July 2010

SUMMARY OF PRODUCT CHARACTERISTICS

Section 4.4

There have been post-marketing reports of severe skin reactions (e.g. erythema multiforme (EM), Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN)) associated with isotretinoin use. As these events may be difficult to distinguish from other skin reactions that may occur (see section 4.8), patients should be advised of the signs and symptoms and monitored closely for severe skin reactions. If a severe skin reaction is suspected, isotretinoin treatment should be discontinued.

Section 4.8

Skin and subcutaneous tissues disorders: 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,
Unknown*	Erythema multiforme, Stevens-Johnson Syndrome, toxic epidermal necrolysis.

PACKAGE LEAFLET

Possible side effects

Skin and hair problems Unknown frequency

Serious skin rashes (erythema multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis), which are potentially life-threatening and require immediate medical attention. These appear initially as circular patches often with central blisters usually on arms and hands or legs and feet, more severe rashes may include blistering of the chest and back. Additional symptoms such as infection of the eye (conjunctivitis) or ulcers of the mouth, throat or nose may occur. Severe forms of rash may progress to widespread peeling of the skin which can be life threatening. These serious skin rashes are often preceded by headache, fever, body aches (flu-like symptoms).

If you develop a rash or these skin symptoms, stop taking Roaccutane and contact your doctor immediately.

* cannot be estimated from the available data