

**CONDITIONS DE PRESCRIPTION ET DE DELIVRANCE DE L'ACITRETINE  
(SORIATANE®) CHEZ LES FEMMES EN AGE DE PROCREER ENTRE 2007 ET 2012**

**Compliance with pregnancy prevention plan recommendations in  
8672 French women of childbearing potential exposed to acitretin**

**Abstract**

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**Purpose:** Acitretin is an oral synthetic aromatic analogue of retinoic acid available in most European countries since 1988. It is mainly used to treat severe psoriasis. Like all systemic retinoids, acitretin is teratogenic. Strict pregnancy prevention is required in women of childbearing potential who use acitretin. This study assessed compliance with Pregnancy Prevention Plan (PPP) recommendations, specifically looking at compliance with pregnancy testing (PT) and pregnancy occurrence.

**Methods:** A cohort of 8672 women aged 15-49 years initiating acitretin treatment from 1 January 2007 through 31 December 2013 was identified using French SNIIRAM (administrative claims data) and PMSI (hospitalisations data) databases. Pregnancy tests (PTs) were identified from reimbursed serum  $\beta$ HCG and urine laboratory PTs. To satisfy PT criteria, patients who started treatment had to undergo a PT within 3 days before acitretin was dispensed. Pregnancies were identified by a pregnancy-related hospital stay or an outpatient medical abortion.

**Results:** A PT was performed in only 12% of women starting treatment and was rarely performed during treatment or during the 24 months following discontinuation of treatment. Compliance with PPP recommendations although poor appeared to be better among private dermatologists, as a PT was performed for 16% of treatment initiations (vs. 4% for general practitioners,  $p < 0.001$ ). Moreover, 470 pregnancies were reported corresponding to 27 pregnancies per 1000 person-years at risk of teratogenicity.

**Conclusions:** This study highlights poor compliance with acitretin PPP recommendations in France. Physicians and pharmacists must more rigorously apply the acitretin PPP recommendations, and patients must be better informed about acitretin's risk of teratogenicity.

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