

# Pierre Fabre

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## DERMATOLOGIE

June 10<sup>th</sup>, 2013

### **Curacne® (Isotretinoin) Pregnancy Prevention Programme**

*Dear Doctor Letter addressed to dermatologist and pharmacist*

Dear Healthcare Professional,

Pierre Fabre would like to advise you with latest regulations with respect to Curacne® 10 and 20 mg (isotretinoin).

Curacne® is indicated in patients with **severe forms of acne** (such as nodular and conglobate acne or acne at risk of permanent scarring) resistant to adequate courses of standard therapy with systemic antibacterial and topical therapy.

The benefit-risk balance of Curacne® was evaluated as favourable in the context of the strict respect for this indication and for the measures of monitoring envisaged by lawful mention.

Regarding teratogenicity of isotretinoin, a risk management plan was set up including a pregnancy prevention programme, educational material and monitoring of high risks linked to the use of this drug.

**Curacne® is contraindicated in women of childbearing potential unless all of the conditions mentioned in the Pregnancy Prevention Programme are met.**

• Prior to starting therapy, the female patients must:

- Be informed and understands the potential consequences of pregnancy and the need to avoid pregnancy.
- Must be provided with comprehensive information on pregnancy prevention and must be provided with medication guide with information about contraception
- Read and sign the care and contraception consent form
- Use two effective methods of contraception, beginning at least one month before the start of treatment with Curacne®
- Provide a medically supervised pregnancy test in the 3 days prior to the first prescription.

• During the therapy, the female patients must:

- Continue to use two effective methods of contraception throughout the duration of treatment
- Provide repeated medically supervised pregnancy tests every month

Dispensing of isotretinoin should occur **within a maximum of 7 days of the prescription.**

**Pierre Fabre would like to remind you that the patient medication guide must be provided to the patient by the pharmacist at each dispensing.**

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• After the end of treatment, the female patients must:

- Continue to use two effective methods of Contraception for at least five weeks after stopping treatment with isotretinoin
- Undergo a final pregnancy test five weeks after stopping treatment.

If **pregnancy occurs in a woman treated with isotretinoin, treatment must be stopped immediately** and the patient should be referred to a physician specialised or experienced in teratology for evaluation and advice.

The information provided in this letter has been reviewed by Saudi Food and Drug Authority.

**Call for reporting**

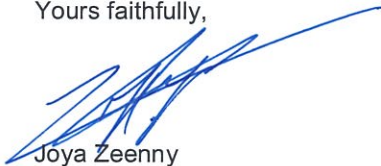
You can assist us by reporting Adverse Drug Reactions to:

- Pierre Fabre
- Dr. Khalid Arnous : Email: [karnous@banaja.com](mailto:karnous@banaja.com) TEL: +966 11 412 4444
- Dr. Joya Zeenny : Email : [Joya.zeenny@pierre-fabre.com](mailto:Joya.zeenny@pierre-fabre.com) TEL :+ 961 1 989840 ext : 128

Or

- SFDA (National Pharmacovigilance and Drug Safety Center)
- E-mail to: [npc.drug@sfd.gov.sa](mailto:npc.drug@sfd.gov.sa)
- Fax: +966 -11- 2057662.

Yours faithfully,



Joya Zeenny

Regulatory affairs and Pharmacovigilance manager Middle East

  
Pierre Fabre