Pierre Fabre
DERMATOLOGIE

June 10th, 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 teratogenecity 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.

• 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 TEL: +966 11 412 4444
- Dr. Joya Zeenny : Email : Joya.zeenny@pierre-fabre.com TEL :+ 961 1 989840 ext : 128

Or

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

Yours faithfully,

Joya Zeenny
Regulatory affairs and Pharmacovigilance manager Middle East

Pierre Fabre