PHARMACIST MATERIALS

Pharmacist Checklist / Guidance for dispensing oral retinoids products containing acitretin, alitretinoin and isotretinoin

Oral retinoids products containing acitretin, alitretinoin and isotretinoin belongs to the retinoid class of drugs that cause severe birth defects. Fetal exposure to these products, even for short periods of time, presents a high risk of congenital malformations and miscarriage.

Oral retinoids products containing acitretin, alitretinoin and isotretinoin are therefore strictly contraindicated during pregnancy and in women of childbearing potential, unless all conditions in these products Pregnancy Prevention Programme are fulfilled.

A negative pregnancy test, issuing a prescription and dispensing oral retinoids products containing acitretin, alitretinoin and isotretinoin should ideally occur on the same day.

If you are aware that a pregnancy has occurred in a woman treated with oral retinoids products containing acitretin, alitretinoin and isotretinoin, treatment should be stopped immediately and the woman should be promptly referred to the prescribing doctor.

If you are aware that a female patient has become pregnant within one month [**3 years for acitretin**] of stopping oral retinoids products containing acitretin, alitretinoin and isotretinoin she should be referred to her prescribing doctor.

As pharmacist, you should only dispense oral retinoids products containing acitretin, alitretinoin and isotretinoin after checking the following information:

For women of child-bearing potential:	
In order to support regular follow up, including pregnancy testing and monitoring, the prescription for oral retinoids products containing acitretin, alitretinoin and isotretinoin should ideally be limited to a 30-day supply.	
All patients should be instructed:	
Never to give the oral retinoids products containing acitretin, alitretinoin and isotretinoin to another person.	
To return any unused capsules to their pharmacist at the end of treatment.	
Not to donate blood during oral retinoids products containing acitretin, alitretinoin and isotretinoin therapy and for one month **after discontinuation [3 years for acitretin]** due to the potential risk to the foetus of a pregnant transfusion recipient	

Reporting of suspected adverse reactions/ exposure during pregnancy

Any suspected adverse reactions or pregnancies occurring during treatment and within 1 month [3 years for acitretin] following discontinuation of treatment should be reported to the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Al. Jerozolimskie 181C, 02-222 Warszawa, tel.: + 48 22 49 21 301, fax: + 48 22 49 21 309, e-mail: ndl@urpl.gov or to Marketing Authorization Holder in Poland.

The **electronic version** of educational materials can be found on the Marketing Authorization Holder's or/and dedicated website.