

Acitretin

Recommendations:

- Amendments to the Product Information

It has been agreed that the following amendments to the Product Information are required:

Section 4.3

The statement that donation of blood is prohibited during and for at least 1 year, must be amended to state that donation of blood is prohibited during and for at least 2 years after completion of treatment with acitretin.

Leaflet wording (if available)

In section 2 (Danish PIL) the statement that donation of blood is prohibited during and for at least 1 year after completion of treatment with acitretin, must be amended to state that donation of blood is prohibited during and for at least 2 years after completion of treatment with acitretin.

Adding of the missing information in section "special precautions" in the danish PIL:

- Increased cardiovascular risk in high-risk patients (diabetes, alcoholism, obesity).
- Mood alterations (irritability, aggression, depression) with high-dose retinoids.
- Not all risks in relation to life-long administration are known.
- Patients should contact their doctor if they experience symptoms of Capillary Leak Syndrome / retinoic acid syndrome or exfoliative dermatitis.
- Due to the risk of foetal malformations, the medicine must not be passed on to other people. Unused or expired products should be returned to a pharmacy for disposal.