Douglas Pharmaceuticals Ltd
Central Park Drive, Lincoln
PO Box 45 027, Auckland 0651
New Zealand
T: +64 9 835 0660 **F:** +64 9 835 0665
www.douglas.co.nz

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Novatretin® (acitretin) 10 mg and 25 mg capsules – Increase in period during which effective contraception must be used has increased from two to three years and important information about blood donations

Dear Healthcare Professional,

Douglas Pharmaceuticals Ltd in agreement with Medsafe, would like to remind you of important changes in the time periods during which effective contraception must be used and blood donations prohibited while being treated with Novatretin capsules .

Summary:

- Acitretin, the active ingredient in both strengths of Novatretin capsules is contraindicated in women of childbearing potential unless all conditions of the pregnancy prevention program detailed in the product datasheet[1] are met.
- The period during which effective contraception must be used has increased from two to **three years** after the end of treatment.
- Blood should not be donated by patients while on Novatretin and for three years following completion of treatment.
- Women of child bearing potential must not receive blood from patients being treated with Novatretin.

Further information and recommendations to Healthcare Professionals

Novatretin (acitretin) is a teratogenic medicine used to treat several skin conditions, including psoriasis. It is contraindicated in women of childbearing potential unless they follow all of the conditions of the Pregnancy Prevention Programme[1]. The requirement to take effective contraception following completion of treatment has been changed. Women must now use effective contraception for **three years** (36 months). The change has come about from the finding that etretinate can be formed in the presence of alcohol. The half-life of etretinate is 120 days[1], thereby resulting in the requirement for increased post-treatment contraception.

Prescribers are asked to remind women of childbearing potential of the Pregnancy Prevention Programme requirements for Novatretin. In particular, any woman requiring treatment should understand that she must consistently and correctly use one highly effective method of contraception (ie, a user-independent form) or two complementary user-dependent forms of contraception. Contraceptive use must be for at least one month prior to starting treatment with Novatretin, throughout the treatment period and for at least three years (36 months) after cessation of treatment with Novatretin. Oral progesterone-only contraceptives are not considered an effective form of contraception during treatment with Novatretin[1].

In addition, donation of blood by a patient being treated with Novatretin is prohibited during and for 3 years after completion of treatment with Novatretin. Women of childbearing potential must not receive blood from patients being treated with Novatretin because of the potential risk to the foetus of a pregnant transfusion recipient.

Reporting adverse events

Reporting suspected adverse reactions has an important role in monitoring the benefit/risk balance of medicines. Please report any suspected adverse events via email to Douglas Pharmaceuticals Ltd at drugsafety@douglas.co.nz.

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Alternatively, suspected adverse events may be reported to the Centre for Adverse Reactions Monitoring (CARM) at https://nzphvc.otago.nz/.

If you have any question related to this notification, please contact Douglas Medical Information via Customer Services on 0800 DOUGLAS, 0800 368452.

Yours sincerely,

Roger Smart
Regulatory and Clinical Affairs Strategic Business Partner

Reference

1. Douglas Pharmaceuticals Ltd. 2019. *Novatretin New Zealand Data Sheet* 8 October 2019. URL: medsafe.govt.nz/profs/Datasheet/n/novatretincap.pdf [accessed 13 May 2021]