

30 October 2024

133 Molesworth Street PO Box 5013 Wellington 6140 New Zealand T+64 4 496 2000

Dear prescribers of isotretinoin

Strengthening Isotretinoin Prescribing Practices

The Ministry of Health was recently informed about the sad death of a young man due to suicide while being treated for acne with isotretinoin. This case highlighted potential gaps in the way people prescribed isotretinoin are informed about risks and how they are monitored.

As you know, isotretinoin is an effective treatment for acne. However, there are risks relating to pregnancy, and physical and psychiatric adverse effects that need careful management. We are writing to request your support in strengthening isotretinoin prescribing practices in New Zealand so that young people with acne receive the best possible care.

Prescribing isotretinoin

Based on learnings from the recent case report, we would like to emphasise the importance of the following steps in isotretinoin prescribing.

- Please refamiliarise yourself with the appropriate use of isotretinoin. This is outlined in the product data sheet (data sheet search). Local information can also be found at Community HealthPathways, bpac^{nz}, and New Zealand Formulary.
- Allow sufficient time to discuss the benefits and risks of isotretinoin and
 other treatment options with the patient (and their whānau/caregiver where
 appropriate). Although not every patient will experience adverse effects, every
 patient should know about them and what to do if they occur. We recommend
 discussing both common and potentially serious but rarer adverse effects and the
 pre-treatment screening and monitoring required to manage these risks.
- Document discussions and decisions. Please ensure that your records accurately reflect the information that was discussed/provided during the informed consent process. We recommend providing written information to supplement discussions. Printable patient information is available online from several trusted sources such as the Consumer Medicine Information sheet (<u>CMI search</u>) or Healthify (<u>healthify.nz</u>).
- Schedule follow-up appointments to monitor treatment effect and adverse effects. Regular follow-up is needed for all patients taking isotretinoin to ensure the treatment is working as intended and is being tolerated with no unacceptable adverse effects.

Pre-treatment screening and monitoring for important risks

The following information is a reminder of some of the important risks of isotretinoin with specific pre-treatment screening and monitoring requirements. This is not intended to be a complete list of adverse effects. For more information refer to the product data sheet (data sheet search).

- Psychiatric adverse effects have been reported in people treated with
 isotretinoin. Successful treatment of acne can improve psychological wellbeing.
 However, serious mood and behavioural disorders have been reported in some
 patients taking isotretinoin. While a causal association has not been definitively
 established, mental health should be assessed before prescribing isotretinoin
 and during treatment.
- **Isotretinoin is highly teratogenic.** Isotretinoin is contraindicated in people who are pregnant or people at risk of becoming pregnant due to the rate of severe birth defects (25-40%) even with a short duration of exposure. Patients must be able to comply with the necessary contraceptive measures and pregnancy must be excluded before starting treatment and, periodically during treatment.
- **Isotretinoin can cause liver function and lipid abnormalities.** These effects are common (up to 25% of patients) and while usually mild, rare cases of hepatitis and pancreatitis have been reported. Serum lipids and hepatic function should be checked prior to starting isotretinoin and periodically during treatment.

We appreciate that the management of acne is complex and there is no one-size-fits all approach to treatment, however we hope you find this information helpful.

We also encourage prescribers to take the time to review the Medical Council of New Zealand (MCNZ) statements on good prescribing practice and informed consent.

Nā māua noa, nā (yours sincerely)

Chris James

Group Manager

Medsafe

Joe Bourne

Chief Medical Officer

Clinical, Community and Mental Health