

ISOTRETINOIN - SAFE PRESCRIBING - HIT THE SPOT!

- ▶ ISOTRETINOIN IS A POTENT TERATOGEN
- ▶ THERE IS POTENTIAL FOR MANY ADVERSE REACTIONS
- ▶ USE ONLY WHERE CLEARLY INDICATED
- ▶ THOROUGH AND EXTENDED CONSULTATIONS ARE REQUIRED AT EACH VISIT
- ▶ PATIENTS REQUIRE APPROPRIATE ON-GOING MONITORING
- ▶ PRESCRIBERS ARE STRONGLY ENCOURAGED TO PARTICIPATE IN FURTHER CME

Isotretinoin is a *high-risk* medicine because it is a potent human teratogen. Foetal damage may occur if taken during pregnancy, including (but not limited to): central nervous system and cardiovascular abnormalities, facial dysmorphism, absence/deformity of ears, and eye problems; these abnormalities have occurred within the therapeutic range – a single dose of isotretinoin may cause harm.

A range of troublesome side-effects may occur in patients. The most common ones include: transient flare of their acne, inflammation of the lips, dry eyes, dry nasal mucosa (nose bleeds), dry skin and photosensitivity, muscle aches, fatigue, visual disturbances, and thinning of scalp hair. Some of these reactions can be relieved with simple interventions (e.g. emollients for dry skin). Rarely, isotretinoin may cause a transient and reversible rise in liver transaminases and serum triglyceride concentrations.

Case reports of mood changes, depression, and suicidal ideation (including suicide attempts) have been reported with isotretinoin use. A direct casual link between isotretinoin and depression has not been clearly established in retrospective studies (probably confounded by the increased prevalence of psychiatric illness among adolescents/patients with acne in general) – also see below.

Prescribers are reminded about the potential harm that may arise from isotretinoin use, particularly following unplanned pregnancies, and to balance these risks against potential benefits. Isotretinoin therapy is usually reserved for (but not limited to): severe or nodulocystic acne, disfiguring acne vulgaris, and moderate/severe cases resistant to routine treatments (e.g. topical agents and oral antibiotics).

Extended consultations are required to ensure isotretinoin is used safely; adequate time is needed to fully discuss the risks and benefits of isotretinoin therapy. This is essential when prescribing isotretinoin to women of child bearing age, as they require rigorous counselling. Patients, especially those with a history of depression, require information about the signs of depression; advise them to report these promptly.

Patients taking isotretinoin should understand the need for rigorous follow-up, preferably on a monthly basis. All patients should be reviewed for signs of depression. For patients presenting with depression, cessation of isotretinoin may be insufficient and a psychiatric or other mental health review may be required. Regular pregnancy tests and monitoring of serum lipids/liver function tests are necessary.

Prescribers are strongly encouraged to participate in an accredited/approved training session (e.g. BMJ learning tool through the RNZCGP, and PHARMAC seminars), and to use a decision support tool (e.g. the bpac tool).

KEY REFERENCE

Mylan New Zealand Ltd. Isotane capsules data sheet 02/02/09. www.medsafe.govt.nz/profs/datasheet/i/isotanecap.htm (accessed on 11 May 2009).

Acknowledgement

The QUM Team at Waitemata DHB acknowledge Linda Bryant, East Health Trust, for her help with this bulletin.

For further information on isotretinoin and other high-risk medicines along with a full reference list, visit our website at: www.saferx.co.nz