

ISOTRETINOIN - SAFE PRESCRIBING - HIT THE SPOT!

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- ▶ INFORM PATIENTS THAT ISOTRETINOIN IS A POTENT TERATOGEN
- ▶ USE ONLY WHERE CLEARLY INDICATED
- ▶ PRESCRIBE THE LOWEST EFFECTIVE DOSE
- ▶ ADVISE PATIENTS ABOUT THE POTENTIAL FOR ADVERSE REACTIONS
- ▶ PERFORM A THOROUGH CONSULTATION AT EACH VISIT
- ▶ ARRANGE ON-GOING MONITORING

Isotretinoin is indicated for patients with severe forms of nodulocystic acne that are resistant to other therapies. Inform patients about the potential harm that may arise from isotretinoin use, especially the teratogenic effects.

INFORM PATIENTS THAT ISOTRETINOIN IS A POTENT TERATOGEN

Isotretinoin is a potent teratogen and can cause severe foetal malformations. There is an extremely high risk that a deformed infant will result if pregnancy occurs while taking isotretinoin in any amount, even for short periods. Inform patients that they need to continue with contraception for at least 1 month after stopping isotretinoin.

Men taking isotretinoin

No contraceptive precautions are required for males who are taking isotretinoin; birth defects have not been identified in children fathered by men who have taken isotretinoin.

USE ONLY WHERE CLEARLY INDICATED

Isotretinoin should only be considered if the patient has already trialled other available treatments and received an inadequate response. Isotretinoin is contraindicated in:

- women who are pregnant or who may become pregnant
- women who are breastfeeding
- hepatic insufficiency
- hypervitaminosis A
- severe hyperlipidaemia

Note: Inform patients that blood donation is contraindicated during isotretinoin treatment, and for at least 4 weeks following discontinuation.

PRESCRIBE THE LOWEST EFFECTIVE DOSE

Recent evidence suggests that isotretinoin is best prescribed using a lower daily dose, eg 10-20mg daily. Lower doses appear to be as effective as higher doses, and are associated with fewer adverse effects. Isotretinoin is best taken with food to aid absorption. A suggested regimen is to initiate isotretinoin at 10-20mg daily and to continue until all acne

lesions have resolved (usually 3-5 months). Then reduce the dose to 5-10mg daily for a further 2-4 months to avoid relapse and scarring.

Note: The 5mg capsule is not currently subsidised; consider prescribing 10mg on alternate days.

ADVISE PATIENTS ABOUT THE POTENTIAL FOR ADVERSE REACTIONS

A range of troublesome adverse effects can occur with isotretinoin use; these are generally dose-related. Examples include:

- transient flare-up of acne
- inflammation and dryness of the lips
- dry eyes (causing difficulty with contact lens use)
- dry nasal mucosa (and nose bleeds)
- dry skin and photosensitivity
- headaches
- muscle aches (and reduced vigorous exercise tolerance)
- fatigue
- visual disturbances (including night blindness)
- thinning of scalp hair and reversible hair loss
- hyperostosis and bone changes

Some of these reactions can be relieved with simple interventions, eg using emollients for dry skin. Advise patients to protect their skin from direct sunlight and to avoid sunbeds. Patient resources are available via www.dermnetnz.org and www.saferx.co.nz, and the BPAC acne prescribing tool.

Psychiatric side-effects

Mood changes, depression, and suicidal ideation (including suicide attempts) have been reported with isotretinoin use. Assess patients for signs of depression and suicidal thoughts before starting isotretinoin therapy.

Note: A direct causal link between isotretinoin use and depression or suicide has not been clearly established, and studies of mood change have found that mood and wellbeing usually improve as acne improves.

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ISOTRETINOIN

PERFORM A THOROUGH CONSULTATION AT EACH VISIT

Extended consultations are required to ensure isotretinoin is used safely.

Pregnancy

Although the risks of foetal damage are well known, there are still reports of pregnancies occurring with women who have taken isotretinoin. Each woman should understand the implications of pregnancy, and comply with the requirements for contraception.

Medsafe recommends the following approach when prescribing isotretinoin to **ALL** women of childbearing potential:

- take a current sexual history
- take a menstrual history
- arrange a pregnancy test
- provide contraceptive advice
- prescribe contraceptives
- ensure the patient understands the risks
- advise to start taking isotretinoin during their next period
- arrange regular pregnancy tests

Women must practice effective contraception for at least 1 month before starting treatment, during treatment, and for 1 month after stopping treatment. Oral progestogen-only contraceptives are not considered effective, and barrier methods should not be used alone.

Depression

All patients need to be informed about the risk of depression before isotretinoin begins, and be monitored for the development of depression during treatment. Provide patients (and their families) with information about depression and suicidal ideation. Patients should be advised to report symptoms promptly so they can be they can receive appropriate psychiatric support.

Note: Symptoms of depression and suicidal thoughts may not resolve simply by stopping treatment with isotretinoin; continue to assess and monitor these patients.

Cosmetic treatments

Advise patients to avoid **dermabrasion** and **wax epilation** during treatment and for 6 months after stopping isotretinoin due to a risk of scarring and dermatitis.

ARRANGE APPROPRIATE ON-GOING MONITORING

Patients taking isotretinoin should understand the need for rigorous follow-up, and prescribers should consider prescribing **1 month** of isotretinoin at a time to facilitate regular review.

Blood testing

Test required	Before therapy	After one month	During treatment	After treatment
Pregnancy	Yes	Yes	Monthly	1 month after stopping
Serum lipids	Yes	Yes	-	At end of treatment
Liver function	Yes	Yes	Every 3 months	-

Best Practice Decision Support

Special Authority criteria for isotretinoin recommends that a computer-based decision support tool is used when prescribing. 'Bestpractice Decision Support' is a web-based system that helps to support general practice with the assessment of acne, provides access to resources and describes treatment options. The isotretinoin section has information about patient consent, monitoring and prescribing, including quick access to the Special Authority process and patient information.

ACKNOWLEDGEMENTS

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KEY REFERENCES

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CLICK HERE FOR MORE INFORMATION ON ISOTRETINOIN INCLUDING A FULL REFERENCE LIST

For further information on other high-risk medicines visit our website at: www.saferx.co.nz