Position statement

THE AUSTRALASIAN COLLEGE OF DERMATOLOGISTS

Isotretinoin for treatment of acne

Purpose: To provide evidence-based information about the benefits and harms associated with isotretinoin for the treatment of acne in the Australian clinical and regulatory context.

Audience: Health professionals

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Endorsement: This position statement has been approved by The Australasian College of Dermatologists Expert Advisory Committee.

Disclaimer: This position statement reflects the general views of the Australasian College of Dermatologists at the date of release and may be subject to amendment to reflect emerging clinical and scientific evidence. This information provides educational information and is not intended as a substitute for individual patient assessment. Practitioners are advised to interpret and apply recommendations according to the needs and circumstances of each patient.

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Key messages and recommendations

- Isotretinoin (13-cis-retinoic acid) is a natural derivative of vitamin A, binding to and activating nuclear retinoic acid receptors (RARs). The activated RARs serve as transcription factors and lead to the inhibition of sebaceous gland function and keratinisation.
- It is a Schedule 4 medicine, available only by the prescription or order of a specialist dermatologist or physician,[9] with variations in prescribing arrangements across different states and territories.*
- There is robust evidence that the use of isotretinoin is an effective treatment for recalcitrant nodular acne that is resistant to conventional treatment or is causing physical scarring or psychosocial distress. Isotretinoin offers long-term remission for many patients.
- Adverse effects associated with isotretinoin are dose-dependent and reversible (i.e., dryness and cheilitis), except teratogenicity. Adverse effects are generally milder with lower doses of isotretinoin.
- Dose-dependent mucocutaneous clinical adverse effects are most common, but regress with decreases in dose or treatment suspensions.
- Alopecia, headaches, myalgia, tiredness and irritability are uncommon treatment emergent adverse effects. Ophthalmological (other than xerophthalmia) and auditory issues are even less common. Causality is not always clear.
- Isotretinoin is highly teratogenic and should not be prescribed within a month before and during pregnancy under any circumstance.
- The most recent evidence indicates no association between isotretinoin and depression, anxiety and/or suicidal ideation.
- Isotretinoin use significantly improves quality of life among patients with moderate to severe acne.
- There is currently insufficient evidence to suggest an association exists between isotretinoin and sexual dysfunction.
- Safe and effective isotretinoin prescribing requires careful patient selection and individualised treatment, including patient monitoring during the treatment course. To optimise outcomes and to reduce severe teratogenicity risk, the Australasian College of Dermatologists (ACD) supports continued regulation of isotretinoin in Australia.
- A list of key practice points supported with the best available evidence have been developed to assist patients and their prescribers in informed decision-making for the use of isotretinoin in the treatment of acne.

* See *Appendix A, Relevant state and territory legislation relating to isotretinoin prescription*

ACD Position Statement – Isotretinoin for treatment of acne

Background

In Australia, isotretinoin has been available for use since the 1980s, and is recommended to treat acne in patients who have responded poorly to conventional therapy,[1,2] including topical therapies, hormonal agents, and/or systemic antibiotics.[3]

Patients with acne may suffer from poor body image, low self-esteem, experience social isolation and avoid participating in daily activities, which persist long after the active lesions have disappeared.[4] Increased levels of anxiety, anger, depression, and frustration are also observed among patients with acne, often a result of the emotional impact.[4]

Currently, there is no universally accepted clinical grading or classification system for acne in Australia.[3,5] Some dermatologists may use a grading or classification scale by incorporating numbers and types of acne lesions, disease severity, anatomical sites and scarring to guide disease management planning and assess treatment response.[3] Patient-reported outcome questionnaires, including the Dermatology Life Quality Index (DLQI) and Cardiff Acne Disability Index (CADI) are commonly used to assess the psychosocial effects of acne.

Isotretinoin (13-cis-retinoic acid), a natural derivative of vitamin A, is an effective oral retinoid for severe, persistent, or scarring acne.[1,6] Like other retinoids, isotretinoin binds to and activates nuclear retinoic acid receptors (RARs). The activated RARs serve as transcription factors that lead to the inhibition of sebaceous gland function and keratinisation.[1,7]

In acne, isotretinoin:[6]

- reduces the size and activity of sebaceous glands;
- reduces the number of new comedones and cysts;
- reduces anatomical scarring; and
- reduces the anaerobic bacterium, *Cutibacterium acnes*, in the sebaceous gland and upper hair follicle that may contribute to the inflammation seen in acne.

There is sufficient evidence to support the quality, safety, and efficacy for the use of isotretinoin in the treatment for acne.[8]

Regulation and access in Australia

In Australia, medicines are categorised ('scheduled'), under the *Therapeutic Goods Act 1989*, in the interests of public health and safety, placing restrictions around public supply. Schedules are defined in the *Poisons Standard February 2018* and are referred to under state and territory legislation for regulatory purposes.[9]

Isotretinoin is a Schedule 4 medicine, available only by the prescription or order of a specialist dermatologist or physician,[9] with variations in prescribing arrangements across different states and territories. For relevant Australian state and territory legislation and restrictions relating to the prescription of isotretinoin (refer to **Appendix A)**.

Isotretinoin is subsided under the Pharmaceutical Benefits Scheme (PBS) when prescribed for the treatment of severe cystic acne that is unresponsive to conventional therapies.[2] As an authority required (streamlined) medicine, authorised prescribers – specialist dermatologists and physicians – can prescribe isotretinoin without seeking prior approval from the Department of Human Services or the Department of Veterans Affairs.[2]

Dermatologists can prescribe isotretinoin for indications other than that specified by the PBS, including:

- treatment of moderate acne that is resistant to conventional treatment or is causing physical scarring or psychosocial distress;[9] and
- pilosebaceous disorders, such as severe folliculitis, rosacea and hidradenitis suppurativa. [6,7]

However, these prescriptions are 'off-label' and are not eligible for PBS reimbursement.

Evidence-base for isotretinoin use for acne treatment

The purpose of this Position Statement on Isotretinoin for Treatment of Acne is to present existing evidence of the benefits and harms of isotretinoin for the treatment of acne. This Position Statement purposefully excludes evidence from pre-clinical trials and research that is currently being conducted and without results to publish. Future evidence will be considered and incorporated into this Position Statement as it becomes available.

Existing published and peer-reviewed evidence supports the use of isotretinoin in the treatment of severe forms of acne, particularly severe recalcitrant nodular acne or acne which has proven refractory to other forms of therapy.[3,8]

For the purpose of this position statement, the College defines isotretinoin dosages as:

- High dose: > 1mg/kg/day
- Medium dose: 0.4 – 1.0mg/kg/day
- Low dose: 0.1 – 0.4 mg/kg/day
- Fixed low dose: 5 – 20 mg /day or less often, irrespective of body weight
- Intermittent dose: 0.5 mg/kg/day for 7 days per month (aligned to menstrual cycle)

Evidence to support this statement is summarised below.

Evidence limitations

The majority of the studies within existing published literature that informed this Position Statement compared different regimens, doses or formulations of oral isotretinoin. The heterogeneity in the studies precluded meta-analysis, which makes it difficult to draw conclusions from the evidence on the recommended dosage and treatment duration of isotretinoin.

Isotretinoin dosage

The historical dosing regimen has been a 16 week course of isotretinoin (0.5 –1 mg/kg/day).[1] However, evidence suggests that patients who receive a higher daily dose of isotretinoin may experience more pronounced side effects compared to those receiving a lower daily dose. [1, 6,7,10,11]

The variability of dosing regimens of oral isotretinoin is largely based on a patient's tolerability. A number of studies have found that lower dose regimens administered over a longer duration may be equally effective.[7,12,13,14] A systematic review of clinical trials of low dose isotretinoin (0.1 and 0.3 mg/kg/day for ≥6-months) in the treatment of acne reported fewer side effects than the standard or higher doses.[13] Evidence also indicates that continuous low dose (0.25 to 0.4mg/kg/day) or continuous conventional dose (0.5 to 0.7 mg/kg/day) is more effective in reducing inflammatory lesion counts than intermittent treatment for one week each month (0.5 to 0.7mg/kg/day).[14]

Isotretinoin doses as low as 5mg/day may be associated with a reduced risk of scarring and transient acne flare,[7,12] and can be combined with other topical medications for greater effectiveness.[13,15] There is no evidence to support the delay of superficial chemical peels, cutaneous surgery, laser hair removal, and fractional ablative and non-ablative laser procedures. Evidence from a systematic review suggests that these procedures are safe during isotretinoin treatment.[14] Mechanical dermabrasion and fully ablative laser are not recommended.[14]

Relapse after cessation of treatment can occur, and there are several risk factors associated with relapse, including age (≤ 14 years or ≥ 25 years), acne severity, hormonal-related acne and stopping treatment before acne has completely cleared. Cumulative dosing does not prevent relapse, however, maintenance of sebaceous gland suppression either by higher-dose for shorter duration or lower-dose for longer duration delays the time to acne relapse.[7]

Adverse effects linked with isotretinoin

Evidence indicates that adverse effects associated with isotretinoin are mostly dose-dependent and reversible.[13] Many of the adverse effects are similar to those described in patients who take high doses of vitamin A.[1]

Systematic reviews assessing the efficacy and safety profile of isotretinoin have shown that the associated adverse events are generally mild,[14,16] and more frequently reported with daily and continuous use of higher dosage (≥0.5mg/kg/day) of isotretinoin.[17,18,19]

Dose-dependent mucocutaneous clinical adverse effects, such as dryness and cheilitis are common among patients receiving isotretinoin. [1,6,10,11] These effects regress with dose reduction or treatment suspensions,[3] and can be managed with the use of lip, ocular and/or nasal emollients. Nosebleeds can occur due to dryness and thinning of the lining of the nasal passages.[6] Other less common reported treatment emergent adverse effects include alopecia, blurred vision, headaches, impaired night vision (due to functional impairment of rods, a type of photo-receptor cell in the retina), irritability, myalgia, photophobia, temporary hearing loss or hearing impairment, tiredness, and vomiting and diarrhoea.

An association between vitamin A deficiency and night vision impairment may exist among patients treated with isotretinoin.[20]

There is insufficient data to support either an association or causal relationship between isotretinoin use and inflammatory bowel disease (IBD), pancreatitis, tinnitus, and benign intracranial hypertension.[1,6,10,11] A meta-analysis of isotretinoin and IBD found that patients exposed to isotretinoin were at no increased risk of developing IBD compared to those not exposed to isotretinoin .[21]

Isotretinoin has the potential to also affect the metabolic system, reflected in altered liver function tests and elevated blood lipids.[5] However, findings from a meta-analysis and systematic review indicate that the proportion of patients with clinically relevant laboratory abnormalities is low.[10,16]

Consideration in women of child-bearing age – Teratogenicity

The most serious risk associated with isotretinoin use is teratogenicity.[1,6,14] 15-35% of pregnancies exposed to isotretinoin result in miscarriage and embryopathies, and serious congenital anomalies.[22] Under the *Poisons Standard February 2018*, if the patient is a woman of child-bearing age, the prescriber must: (1) ensure that the possibility of pregnancy has been excluded prior to commencement of treatment; and (2) advise the patient to avoid becoming pregnant during and for a period of 1 month after completion of treatment.[9] Isotretinoin does not affect female or male fertility in the long-term, nor does it cause birth defects in the offspring of males undergoing treatment.[1,6]

Blood from patients taking isotretinoin will not be accepted by blood banks, due to potential teratogenic effects.[23]

Sexual dysfunction

There is currently insufficient evidence that a causal association exists between isotretinoin and sexual dysfunction.

Observational studies examining a possible link between isotretinoin and sexual dysfunction are limited and often contain small numbers of patients.[24,25] The UK Commission on Human Medicines released an independent report which investigated reports of sexual problems occurring while taking isotretinoin.[26] However, the evidence of a possible association is of low level and is largely derived from reports submitted to adverse event databases. ACD will continue to monitor the extent of the risk.

Isotretinoin is most commonly prescribed in adolescence. Several population-based studies have indicated that sexual functioning issues are common in adolescence due to the complex interplay of physical, social and emotional factors in this age group.[27,28,29] The large British study, Natsal-3 found that of sexually active 16- to 21-year olds, 9% of men and 13% of women reported a distressing sexual problem lasting 3 months or more in the past year.[30]

Isotretinoin and mental health

The majority of peer-reviewed literature does not support a causal association between isotretinoin and depression, anxiety and/or suicidal ideation in acne patients.[31,32,33,34,35,36,37]The UK's Medicines and Healthcare Products Regulatory Agency (MHRA) has concluded that acne itself may be linked to psychiatric disorders.[32]

A study has found that isotretinoin was associated with a reduced incidence of adverse psychiatric outcomes compared with oral antibiotics.[38]

Impact of isotretinoin on quality of life

Positive associations have been observed between isotretinoin use and quality of life (QoL) among acne patients.[39,40,41] A longitudinal, retrospective study found that after two months of isotretinoin treatment, there was more than a 50% improvement in QoL, especially in emotional domain scores among patients with moderate to severe acne.[39] The negative impact on QoL, measured with Skindex-16 scores, showed nearly a 5-fold improvement in QoL from baseline with a full course of isotretinoin.[39]

At the completion of a full course of isotretinoin, the level of patient satisfaction also increases with significant improvements in clinical symptoms and social life reported.[40]

Best practice management to prescribing isotretinoin in the treatment of acne

A list of key practice points to assist patients and their prescribers in informed decision-making for the use of isotretinoin in the treatment of acne have been developed. These practice points are supported with the best available evidence and provide advice on how to appropriately use isotretinoin when treating patients diagnosed with acne, and for the prevention or management plan of adverse effects, such as mental health problems.

Key practice points

Dermatologists treating acne may choose a clinical grading or classification scale – incorporating numbers and types of acne lesions, disease severity, anatomical sites scarring and psychological impact – and use consistently to guide disease management planning and assess treatment response.[3]

Isotretinoin treatment (including dosage and duration) should be decided on a case-by-case basis depending on patient characteristics and expectations. While low doses of isotretinoin (0.1- 0.4 mg/kg/day) are effective, causing fewer adverse effects, it may need to be taken for longer compared to conventional dosing (0.5-1.0mg/kg/day) to see improvements in acne.

Isotretinoin is contraindicated for patients who are: breastfeeding; have severely impaired liver function; have clinically significant abnormal lipid levels; have a known hypersensitivity to retinoids or capsule ingredients (i.e. soya oil); or have pre-existing hypervitaminosis A.[1,6] Dermatologists should ask their patients if they are taking tetracyclines such as minomycin or doxycycline.

All health professionals involved in the care of women of childbearing age and are being treated with isotretinoin should recommend the ongoing and strict compliance of reliable contraception throughout the treatment period and for one month thereafter.[1,6] The treating dermatologist should also have discussions with all women of childbearing age about the risks of isotretinoin treatment and pregnancy and needs to be satisfied that pregnancy has been excluded. Pregnancy testing prior to the initiation of treatment is strongly advised. If pregnancy does occur, isotretinoin must be stopped immediately, and the patient referred to a high-risk pregnancy service.

Laboratory testing (i.e., liver function tests, triglyceride) for metabolic abnormalities prior to the initiation of treatment and subsequently as clinically indicated.[42]

As patients with acne are at an increased risk of depression, clinical assessment of the mental health of patients should occur, including assessing the impact that the patient's acne has on their quality of life. Where prior mental illness has been identified, psychological monitoring and treatment should be undertaken in collaboration with the patient's GP or mental health practitioner.

Health professionals should advise patients of the possible association between acne and mood disturbances and for the need to report any mental health symptoms whilst on any form of acne treatment, including isotretinoin.[7] If appropriate, patients should be screened and monitored for signs of mental ill-health and referred for appropriate management if necessary.[32,33,34]

As isotretinoin is considered hazardous in aviation, patients should not use isotretinoin without express clearance by Civil Aviation Society Australia (CASA) or their Designated Aviation Medical Examiners (DAMEs).[43,44]

Patients should regularly monitor for any signs of serious treatment emergent adverse effects and inform the treating dermatologist, who may discontinue treatment if necessary.

Capsule ingredients in isotretinoin may contain traces of arachidic acid, but a reaction in patients with peanut allergy is rare. There are also no conclusive findings that suggest ingredients in isotretinoin can trigger coeliac disease.

Avoid exposure to intense sunlight or UV rays.[1,6] For effective sun protection of the skin and eyes, a combination of measures is recommended including the wearing of sun protective clothing, correct use of a broad-spectrum sunscreen, wearing of a broad-brimmed hat and sunglasses.

ACD Position Statement – Isotretinoin for treatment of acne

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Appendix A: Relevant state and territory legislation relating to isotretinoin prescription

State / territory	Relevant state / territory legislation	Restrictions
NSW	*Poisons and Therapeutic Goods Act 1966* and *Poisons and Therapeutic Goods Regulation 2008*	Dermatologists are authorised prescribers of oral isotretinoin. Other practitioners are required to apply to NSW Health for an authority and obtain supporting documentation from the patient's current prescriber, a specialist who is authorised to prescribe (a dermatologist).
QLD	*Medicines and Poisons (Medicines) Regulation 2021 (MPMR)*	Dermatologists and specialist physicians in general medicine may prescribe isotretinoin. Other prescribers may apply to Qld Health for a prescribing approval to treat patients with isotretinoin. Applicants must enter into supervisory arrangements with a dermatologist or specialist physician in general medicine.
VIC	*Drugs Poisons and Controlled Substances Act 1981 & Regulations 2017*	Treatment may only be initiated by a medical practitioner who has the appropriate qualifications (FACD) and who holds a **warrant**. Each prescription must include their warrant number. A medical practitioner who does not hold a warrant (e.g. a general practitioner) may only prescribe when acting in accordance with the direction of the warrant holder who is treating the patient.
SA	*Controlled Substances Act 1984* and *Controlled Substances (Poisons) Regulations 2011*	Isotretinoin (for internal use) may only be supplied if prescribed or ordered by a specialist in dermatology, oncology or haematology (or a medical registrar working under such a specialist), or such other specialist individually authorised by the Minister.
TAS	*Poisons Act 1971 and Poisons Regulations 2018*	Isotretinoin may be prescribed by a dermatologist and specialist physician who holds a licence, permit or authority.
ACT	*Medicines, Poisons and Therapeutic Goods Act 2008*	Standing approval for: specialist practising in specialist area of dermatology and specialist physician (note: specialist includes a doctor training in a specialist area)
WA	*Medicines and Poisons Act 2014 and Regulations 2016*	Under previous Regulations, isotretinoin or a substance containing isotretinoin was not to be prescribed except by a physician or dermatologist. Prescribing restrictions pertaining to several classes of medications were removed from the Regulations in January 2017.
NT	*Medicines, Poisons and Therapeutic Goods Act 2012*	NT Medicines, Poisons and Therapeutic Goods Act has adopted by reference the 'Standard for the Uniform Scheduling of Medicines and Poisons' (SUSMP). Isotretinoin available only from or on the prescription or order of a dermatologist or specialist physician.

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