

How to .. Prescribe Isotretinoin

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GP CME

Rotorua June 12, 2010

Personal statement

- Experienced dermatologist and have treated thousands of patients with isotretinoin
- I have written or edited articles on management of acne and use of isotretinoin
- These include most of recommended resources
- Douglas Pharmaceuticals, manufacturers of OrataneTM, sponsors DermNetNZ, from which I derive an income

Outline of this presentation

- An overview of isotretinoin
 - When & how
 - Risks & complications
- This lecture does **not** constitute ‘training’ in the use of isotretinoin for acne

Hype

News

Regular news from the New Zealand Doctor newsroom

GPs welcome decision on acne drug



UPFRONT

www.bpac.org.nz keyword: isotretinoin

The isotretinoin debate

Should we be arguing about who is prescribing isotretinoin or is the real issue how it is being prescribed?



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 Isotretinoin deadline this weekend

27/02/2009

[Read more about "Isotretinoin deadline this weekend"...](#)

 2008-11-21-The-RNZCGP-submission-to-PHARMAC-re-isotretinoin.pdf

[Read more about "2008-11-21-The-RNZCGP-submission-to-PHARMAC-re-isotretinoin.pdf"...](#)

 Huge step forward for vocationally registered GPs

*27/02/2009 *

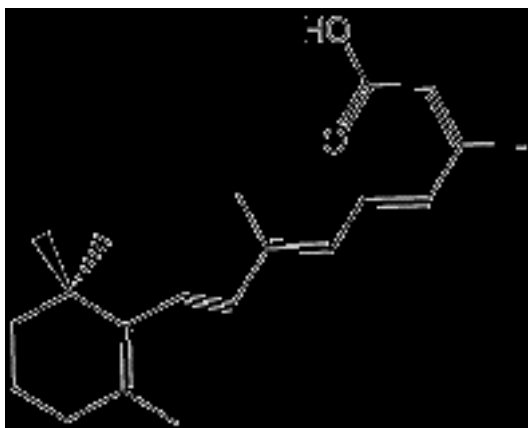
[Read more about "Huge step forward for vocationally registered GPs"...](#)

 ePulse V11 number 8

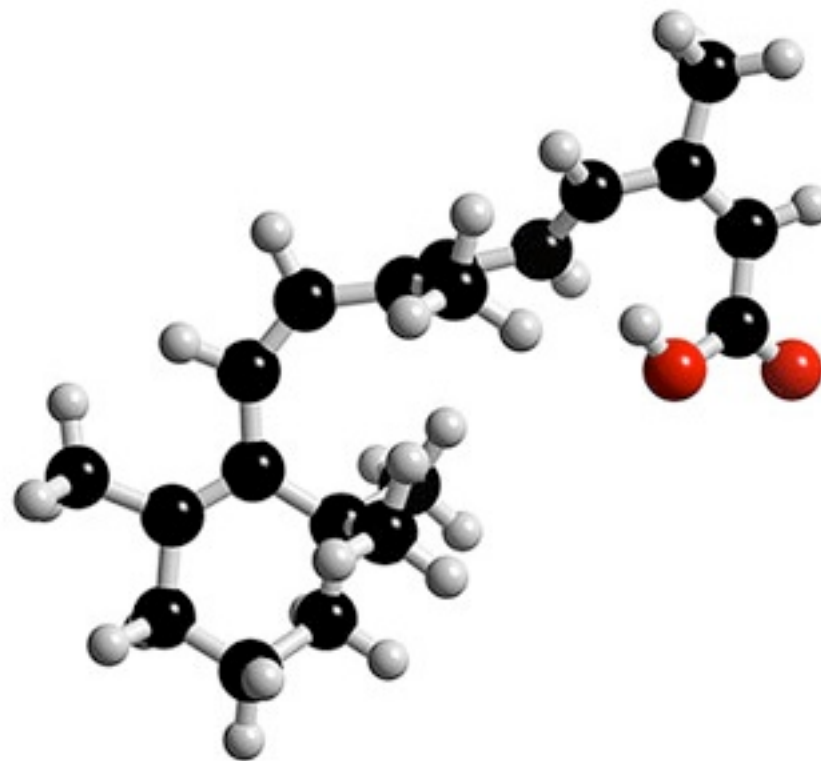
Huge step forward for vocationally registered GPs From 1 March 2009, vocationally registered general practitioners who are able to satisfy the Special Authority requirements will be able to prescribe isotretinoin to patients who meet the Special Authority criteria, and these patients will be able to have the benefit of PHARMAC funding.

[Read more about "ePulse V11 number 8"...](#)

What is isotretinoin?



20mg, 10mg & 5mg capsules



13-cis retinoic acid

What is it used for?

Dermatologists prescribe isotretinoin for patients with acne in the following circumstances:

- Nodular or **nodulocystic acne** (i.e. where there are large deep lumps)
- **Acne conglobata** or **acne fulminans**
- Severe disfiguring inflammatory **acne vulgaris**
- Acne which is resulting in **scarring**
- Moderate acne which has failed to respond to **topical agents** combined with oral **antibiotics**, or in women, **hormonal treatment**
- Acne which relapses rapidly on discontinuing treatment
- Acne which has persisted for several years, or arises in an individual over 25 years old
- **Dysmorphophobic acne**
- When the acne has a significant adverse occupational, social or **psychological** effect on the patient's life

Isotretinoin is also useful for patients severely affected by other follicular conditions. These include:

- **Acne keloidalis nuchae**
- **Chloracne**
- **Gram negative folliculitis**
- **Hidradenitis suppurativa**
- **Oil folliculitis**
- **Pityrosporum folliculitis**
- **Pseudofolliculitis barbae**
- **Pyoderma faciale**
- **Rosacea & rhinophyma**
- **Scalp folliculitis & acne necrotica**
- **Sebaceous hyperplasia**
- **Seborrhoea**
- **Steatocystoma multiplex**

Isotretinoin has proved helpful as a second-line treatment for scaly skin conditions and other inflammatory skin diseases such as:

- **Darier disease**
- **Discoid lupus erythematosus**
- **Epidermal naevi**
- **Folliculitis decalvans**
- **Granuloma annulare**
- **Grover's disease**
- **Hidradenitis suppurativa**
- **Ichthyosis**
- **Sarcoidosis**
- **Skin cancers** especially when they arise in those with organ transplants or **xeroderma pigmentosa**

What are its registered indications?

Indications

Severe forms of nodulo-cystic acne which are resistant to therapy, particularly cystic acne and acne conglobata, especially when the lesions involve the trunk. ORATANE should only be prescribed by physicians who are experienced in the use of systemic retinoids, preferably dermatologists, and understand the risk of teratogenicity if ORATANE is used during pregnancy.



• SA0955 – Isotretinoin (1 page, 3 KB)

<http://www.pharmac.govt.nz/2010/06/01/SA0955.pdf>

Ministry of Health
Phone 0800 243 686

APPLICATION FOR SUBSIDY
BY SPECIAL AUTHORITY

Page 1
Form SA0955
May 2010

APPLICANT (stamp or sticker acceptable)

PATIENT NH:

REFERRER Reg No:

Reg No:

First Names:

First Names:

Name:

Surname:

Surname:

Address:

DOB:

Address:

Address:

Fax Number:

Fax Number:

Isotretinoin

INITIAL APPLICATION

Applications from any relevant practitioner. Approvals valid for 1 year.

Prerequisites (tick boxes where appropriate)

☐

Patient has had an adequate trial on other available treatments and has failed these treatments or these are contraindicated

and

☐

Applicant is a vocationally registered dermatologist, vocationally registered general practitioner, or nurse practitioner working in a relevant scope of practice

and

☐

Applicant has an up to date knowledge of the treatment options for acne and is aware of the safety issues around isotretinoin and is competent to prescribe isotretinoin

and

☐

Patient is female and has been counselled and understands the risk of teratogenicity if isotretinoin is used during pregnancy and the applicant has ensured that the possibility of pregnancy has been excluded prior to the commencement of the treatment and that the patient is informed that she must not become pregnant during treatment and for a period of one month after the completion of the treatment

or

☐

Patient is male

Note:

Applicants are recommended to either have used or be familiar with using a decision support tool accredited by their professional body.

RENEWAL

Current approval Number (if known):

Applications from any relevant practitioner. Approvals valid for 1 year.

Prerequisites (tick boxes where appropriate)

☐

Patient has had an adequate trial on other available treatments and has failed these treatments or these are contraindicated

and

☐

Applicant is a vocationally registered dermatologist, vocationally registered general practitioner, or nurse practitioner working in a relevant scope of practice

and

☐

Applicant has an up to date knowledge of the treatment options for acne and is aware of the safety issues around isotretinoin and is competent to prescribe isotretinoin

and

☐

Patient is female and has been counselled and understands the risk of teratogenicity if isotretinoin is used during pregnancy and the applicant has ensured that the possibility of pregnancy has been excluded prior to the commencement of the treatment and that the patient is informed that she must not become pregnant during treatment and for a period of one month after the completion of the treatment

or

☐

Patient is male

Note:

Applicants are recommended to either have used or be familiar with using a decision support tool accredited by their professional body.

I confirm the above details are correct and that in signing this form I understand I may be audited.

Signed: Date:

Post application to Ministry of Health, Private Bag 3015, Wanganui – Fax: 0800 100 131

Rules for Special Authority funding

Isotretinoin

INITIAL APPLICATION

Applications from any relevant practitioner. Approvals valid for 1 year.

Prerequisites (tick boxes where appropriate)

- ☐ Patient has had an adequate trial on other available treatments and has failed these treatments or these are contraindicated
and
☐ Applicant is a vocationally registered dermatologist, vocationally registered general practitioner, or nurse practitioner working in a relevant scope of practice
and
☐ Applicant has an up to date knowledge of the treatment options for acne and is aware of the safety issues around isotretinoin and is competent to prescribe isotretinoin
and
- ☐ Patient is female and has been counselled and understands the risk of teratogenicity if isotretinoin is used during pregnancy and the applicant has ensured that the possibility of pregnancy has been excluded prior to the commencement of the treatment and that the patient is informed that she must not become pregnant during treatment and for a period of one month after the completion of the treatment
or
☐ Patient is male

Note:

Applicants are recommended to either have used or be familiar with using a decision support tool accredited by their professional body.

Training for GPs

- BMJ Learning
- BPAC article
- BPAC Decision support tool

- DermnetNZ

<http://dermnetnz.org>

- Drug company information

<http://www.oratane.co.nz>

- Medsafe data sheet

<http://medsafe.govt.nz/profs/datasheet/o/oratanecap.pdf>

Resources

BMJ Learning

Just in time	
Acne: a guide to prescribing isotretinoin	
Module type	Just in time Want a fast, evidence based update? Here are the essentials on everyday conditions. Before you start a learning resource it is best to add it to your plan first.
What's in this case:	Acne: a guide to prescribing isotretinoin View user opinions
Target audience	GPs
Author:	Marie Hartley, Les Toop, and Amanda Oakley
Biography:	Dr Marie Hartley is a medical writer for Pegasus Health, an independent GP association in Christchurch, New Zealand. Professor Toop is head of the Department of Public Health and General Practice at the Christchurch School of Medicine, University of Otago, New Zealand. In addition to his clinical role, he is involved in both undergraduate and postgraduate teaching and is the clinical leader of education for Christchurch General Practitioners. His special interests include clinical research (to inform practice), and advocacy for the provision of independent consumer health information and the promotion of professionally driven continuing education. He is past chair of the National Preferred Medicines Centre and is on the Board of Directors of a number of primary care organisations. He is a member of the council of the Royal New Zealand College of General Practitioners. Professor Amanda Oakley is a specialist dermatologist and clinical director of the Department of Dermatology at Health Waikato, New Zealand. She is a clinical associate professor at Waikato Clinical School (Auckland University School of Medicine) and President-Elect of the New Zealand Dermatological Society. Professor Oakley manages the society's web site, NZ DermNet and has special interests in online medical education and teledermatology.
Resource provider:	BMJ



Article is 1.1 yrs

Search by: [Keyword](#) [Publication](#) [Date](#)

How to treat acne

- Key concepts
- Acne diagnosis is based on history and examination
- Examination and assessment of severity
- Pharmacological treatment of acne
 - Mild acne | Moderate acne | Isotretinoin for severe acne
- Isotretinoin is a teratogen
- References
- Issue 20 Contents



Full colour PDF of the pages as they appeared in 'best practice'.

 [Printer friendly PDF.](#)

Key reviewer: **Dr Amanda Oakley**, Specialist Dermatologist and Clinical Associate Professor, Tristram Clinic, Hamilton

Key concepts:

• An inflammatory response to <i>P. acnes</i> results in papules, pustules and inflamed nodules • Acne severity (mild, moderate or severe) may be based on the number, type and distribution of lesions • Benzoyl peroxide, topical retinoids or topical antibiotics are suitable for mild acne • Oral antibiotics may be suitable for moderate acne	• Combined oral contraceptives may be effective for moderate acne in women • Isotretinoin may be suitable for severe acne, although it has many adverse effects and requires close monitoring and management - isotretinoin is a major teratogen, it is essential that women taking isotretinoin do not get pregnant
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DermNet NZ

douglass

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Commitment to Science & Healthcare in New Zealand

Ad

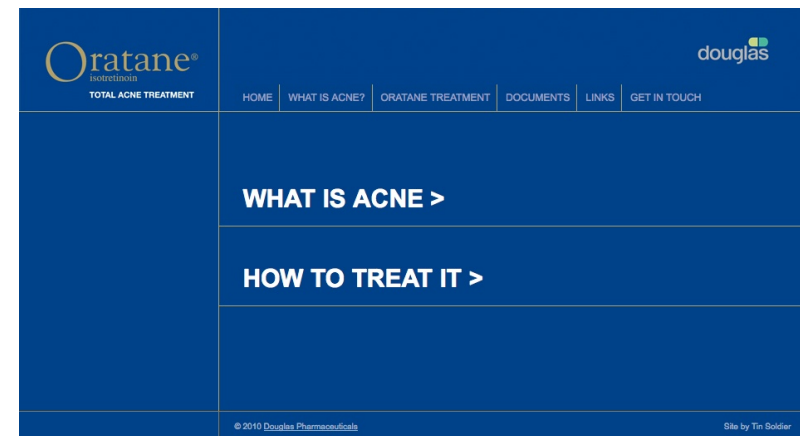
Facts about skin from the New Zealand Dermatological Society Incorporated.
Topic index:
A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

DermNetNZ	Contents	Topics A-Z	CME	Find NZ dermatologist	About us	Contact us	Glossary		Search
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Home | Skin treatment

Isotretinoin

Properties | Indications for treatment | Dosage | Side effects | Drug interactions
Monitoring | Pregnancy | Slow responders | Relapses



ORATANE

Isotretinoin 5 mg, 10 mg, 20 mg and 40 mg Capsules



In response to these concerns PHARMAC states that:

- GPs will receive training in prescribing and managing isotretinoin. It is anticipated that the RNZCGP will accredit and promote relevant training programmes
- If more people are taking isotretinoin, then there may be an absolute increase in the number of affected pregnancies, but the proportion of affected pregnancies will not necessarily be expected to increase. GPs will also be encouraged to be vigilant about giving contraception and pregnancy advice
- GPs are well placed to know a patient's medical history and be better positioned to detect symptoms of mental ill-health including depression and suicidal thoughts
- The pressure to prescribe is equally present for any type of doctor

PHARMAC says its decision was motivated by a desire to combat equity of access issues. Analysis of subsidised isotretinoin use showed that a person was 2.5 times more likely to be using this drug if they were living in the least deprived area (quintile 1) of New Zealand.**

Upfront:- The isotretinoin debate from 'best practice' April 2009

There are two major safety concerns with isotretinoin :

- It is teratogenic at all therapeutic doses and durations of exposure
- It may be linked to depressive illness or suicidal ideation

Decision support

Acne Management (includes Isotretinoin)  DECISION SUPPORT FOR HEALTH PROFESSIONALS

< Page 1 > Data Resources Part Main Menu Send Feedback Logout

Patient Details

NHI		
Family Name		
First Name(s)		
Date of Birth (dd/mm/yyyy)		Age 0
Ethnicity	Please Select	
Ethnicity	Not stated	
Ethnicity	Not stated	
Gender	☐ Male ☐ Female	

Patient Assessment

 Type of Acne ☐ Mild ☐ Moderate ☐ Severe ☐ Nodulocystic

Location of Acne ☐ Face ☐ Back ☐ Upper Trunk

☐ Shoulders ☐ Other

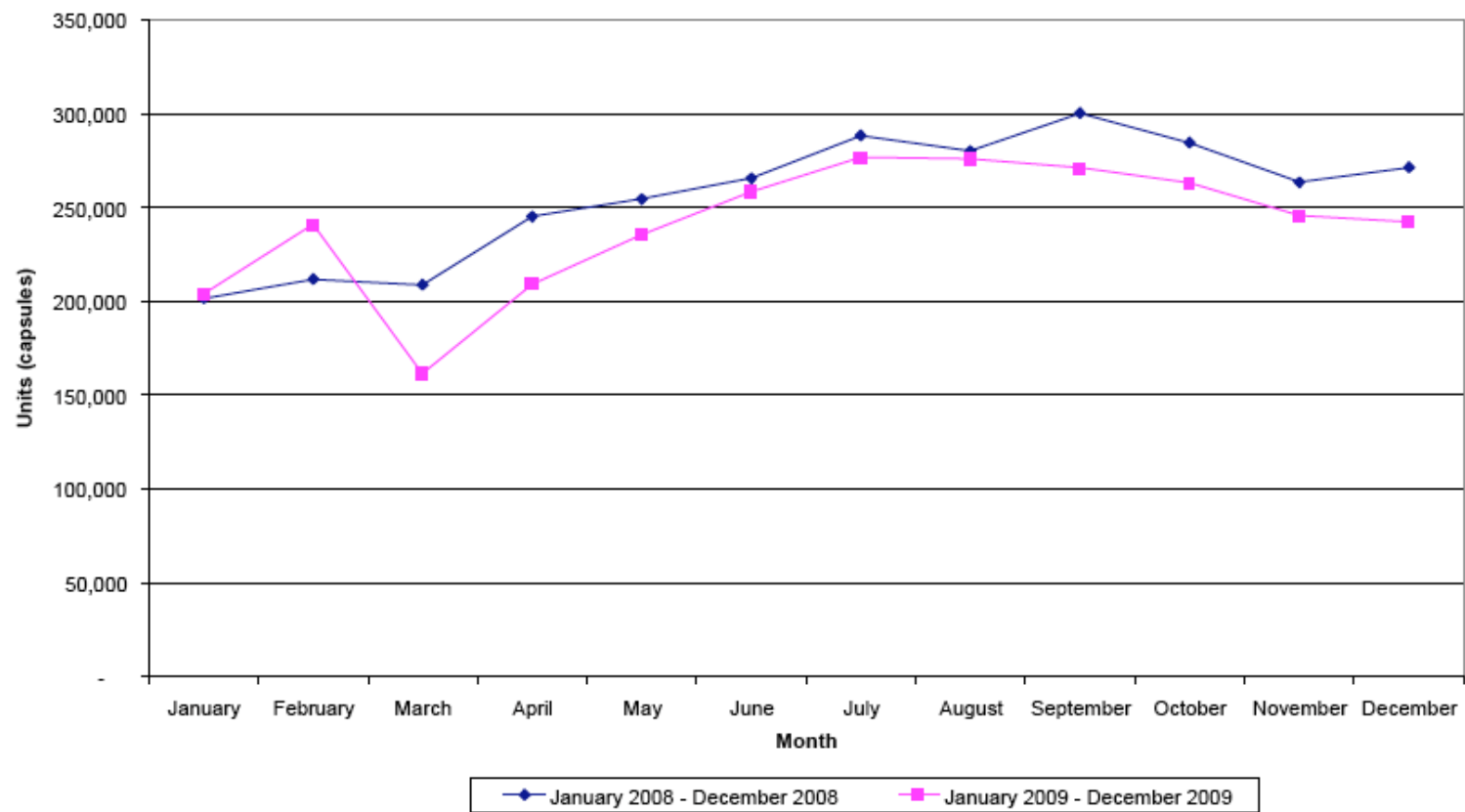
Have you tried OTC treatments? ☐

© bestpractice 2005 - 2010

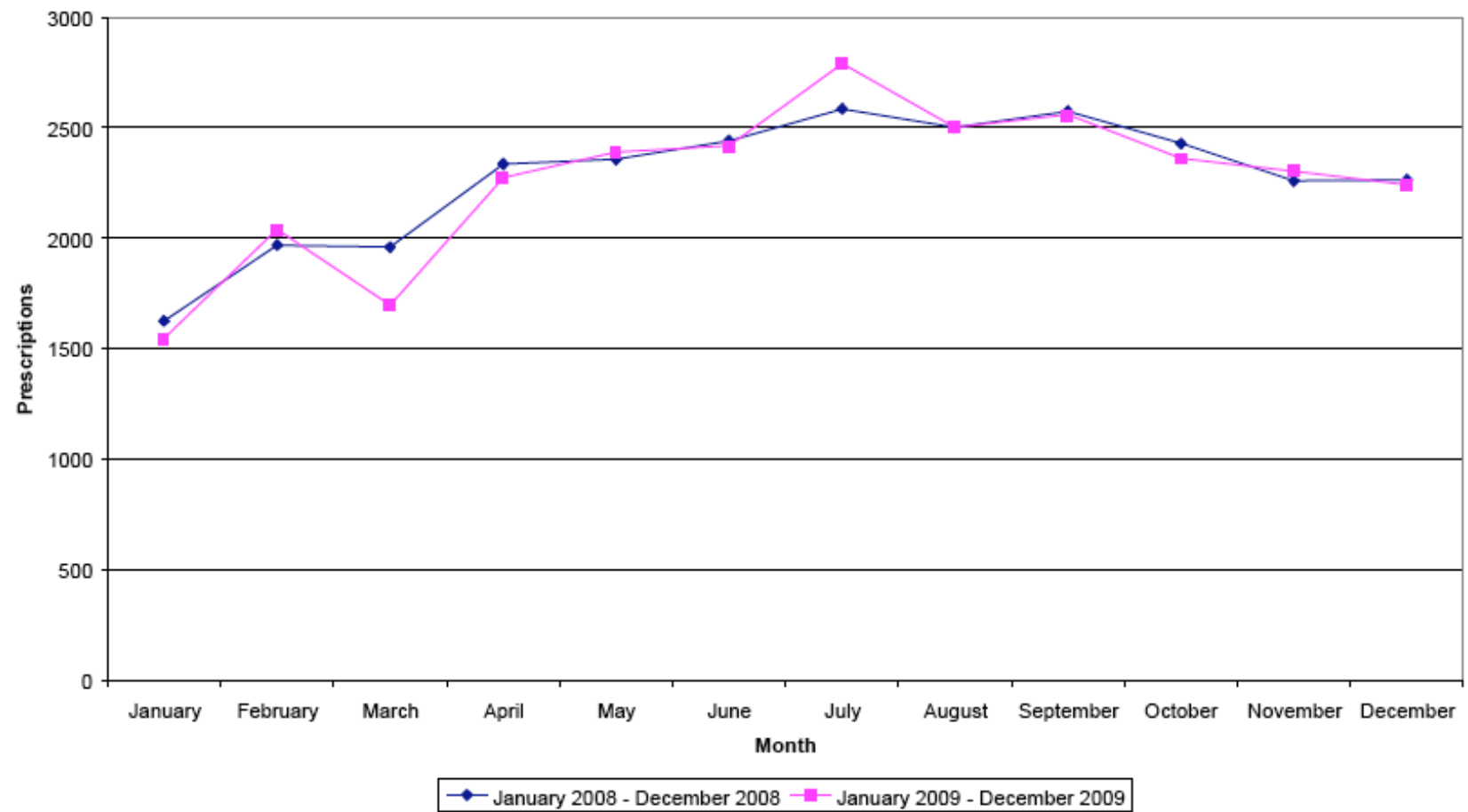
<https://bestpractice.org>

PHARMAC statistics

Isotretinoin Units (2008 - 2009)



Isotretinoin Prescriptions (2008 - 2009)



Lack of GP experience

Isotretinoin:

- Patients with any prescription from a GP: 3,221
- Patients with prescriptions only from a GP: 2,017
- Patients with a prescription from both a GP and specialist: 1,168
 - Note the above two do not sum due to a few patients receiving prescriptions from another category of doctor, e.g. Registrar or Locum or Nurse Practitioner
- GP prescribers: 1,219
 - GPs prescribing to less than 5 patients: 1,063
 - GPs prescribing to between 5 and 9 patients: 122
 - GPs prescribing to between 10 and 29 patients: 32
 - GPs prescribing to 30 or more patients: 2

Gaining experience

- 4 years supervision for dermatology trainees
 - No independent prescribing for 6 months
 - All acne patients discussed with dermatologist
 - Consultant applies for Special Authority
- 300 acne consults / 12 mths at Waikato Hospital
 - Most patients are prescribed isotretinoin
- Equivalent training not achievable for GPs
 - Could develop acne as a subspecialty interest if >50 patients per year

What is acne?

- Folliculocentric inflammatory skin disease
- Characterised by polymorphic lesions
 - Inflamed papules, pustules, nodules
 - Non-inflamed comedones, cysts
 - Secondary crusting, macules, scars
- Face, neck, trunk and sometimes elsewhere

Pathogenesis

- Androgenic stimulation for sebum production
- Hyperkeratinisation of hair follicle
- Colonisation of blocked follicle with *Propionibacterium acnes*
- Free fatty acids from sebum breakdown
- Inflammatory cytokines against bacteria

Grading acne

- Grading scales available e.g., Leeds
- Ask the patient!
 - Clinically mild acne may have serious impact
 - Clinically severe acne may not bother him/her

Acne grading scales



Comedonal acne

Closed comedones



Open comedones



Who needs isotretinoin?

Inflammatory acne

Papulopustular acne



Sandpaper acne



Acne excorié

Hyperpigmentation



Hypopigmentation



Nodulocystic acne

Mixed lesions

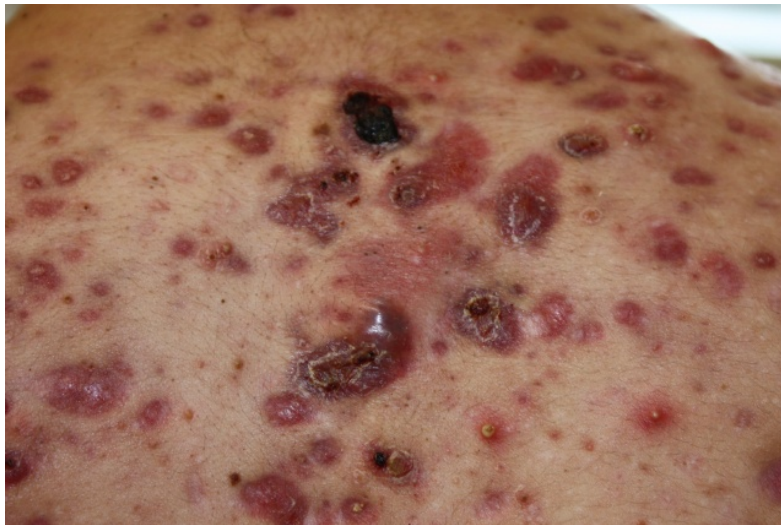


Nodules and cysts



Acne conglobata

Draining sinuses



Crusted sores



Acne fulminans

- Severe inflammatory acne
- Fever, malaise
- Arthralgia, myalgia
- Bone pain
- Neutrophil leucocytosis



Postinflammatory changes

Erythema - weeks



Pigment - months



Acne scarring

Ice pick



Perifollicular elastolysis



Acne scarring

Hypertrophic / keloidal



Atrophic / boxcar



Global Alliance to Improve Outcomes

- Recommendations for management of acne 2003
- Updated 2009

Global Alliance Acne Treatment Algorithm

Acne Severity	MILD MODERATE SEVERE				
	Comedonal	Mixed and Papular/pustular	Mixed and Papular/pustular	Nodular(2)	Nodular/Conglobate
1 ST Choice	Topical Retinoid	Topical Retinoid + Topical Antimicrobial	Oral Antibiotic + Topical Retinoid +/- BPO	Oral Antibiotic + Topical Retinoid + BPO	Oral Isotretinoin ⁽²⁾
Alternatives (1)	Alt. Topical Retinoid or Azelaic acid* or Salicylic acid	Alt. Topical Retinoid Antimicrobial Agent + Alt. Topical Retinoid or Azelaic Acid*	Alt. Oral Antibiotic + Alt. Topical Retinoid +/- BPO	Oral Isotretinoin or + Alt. Topical Retinoid +/- BPO/Azelaic Acid*	High Dose Oral Antibiotic + Topical Retinoid + BPO
Alternatives for Females (1,4)	See 1st Choice	See 1st Choice	Oral Antiandrogen ⁽³⁾ + Topical Retinoid/ Azelaic Acid* +/- Topical Antimicrobial	Oral Antiandrogen ⁽³⁾ + Topical Retinoid/ +/- Oral Antibiotic +/- Alt. Antimicrobial	High Dose Oral Antiandrogen ⁽³⁾ + Topical Retinoid +/- Alt. Topical Antimicrobial
Maintenance Therapy	Topical Retinoid		Topical Retinoid +/- BPO		

1. Consider physical removal of comedones. 2. With small nodules (<0.5 cm). 3. Second course in case of relapse. 4. For pregnancy, options are limited. 5. For full discussion, see Gollnick H, et al. JAAD. 2003.49 (Suppl):1-37.

Mild acne: treatment - topicals first

- Topical retinoid
- Benzoyl peroxide
- Salicylic acid
- Azelaic acid



Isotretinoin if persistent, patient over 25 years, significant distress

Topical retinoids

- Tretinoin
 - ReTrieve® cream 50g 0.5mg/g
 - PHARMAC fully funded from 1 July 2010
 - Retin-A® cream 20g
 - Retinova® emollient cream 20g
- Isotretinoin
 - Isotrex® gel 30g
- Adapalene
 - Differin® gel, cream 30g

Moderate acne: treatment – add oral

- Topical retinoids + benzyol peroxide
- Oral antibiotic
 - Doxycycline
 - Others
- OCP
 - Combined
 - Yasmin / Yaz
 - Ginet-84 / Estelle 35 / Diane-35



Isotretinoin if persistent, > 6 months tx, patient over 25 years, significant distress

Severe acne treatment: refer

- Start topical retinoid + benzoyl peroxide
- Oral antibiotic
- Phone the dermatologist!
- These are high priority patients & will be seen quickly if your concern is communicated

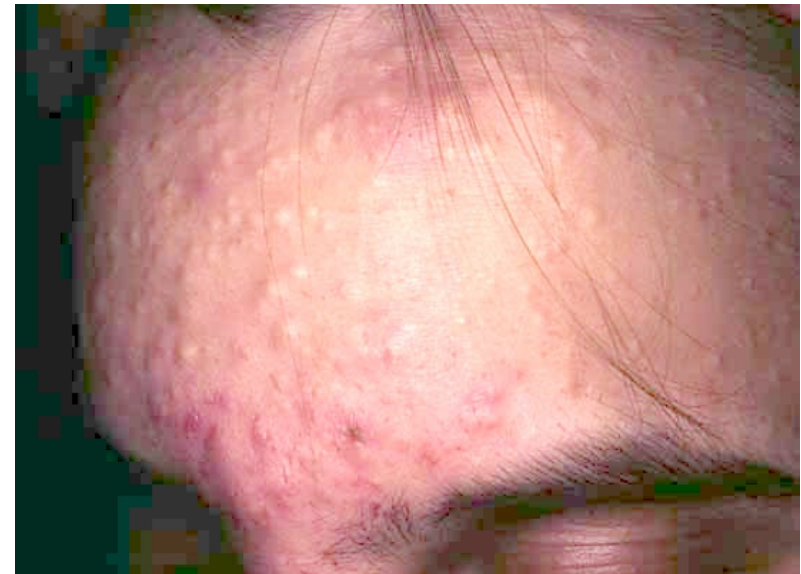


Isotretinoin treatment mandatory but can be very tricky to manage!

When to refer

- If you don't feel confident to prescribe
- If you haven't read all the resources
- Macrocomedones
- Acne conglobata
- Acne fulminans
- Bad nodulocystic disease
- Children

macrocomedones



Risks in children



Use in Lactation

Owing to its lipophilicity, there is a high probability that isotretinoin is secreted into the breast milk. Isotretinoin must not be given to nursing mothers.

Use in Children

Long term use in children under 13 years should be avoided because of a risk of premature epiphyseal closure.

Shared care

- Get to know your local dermatologist(s)
 - Find out if he / she is comfortable with this idea
- Dermatologist initiates treatment
 - Reviews after 3 months
- When access difficult (geographic, financial), GP reviews and prescribes as required
- Good communication required
 - To manage mucocutaneous side effects
 - To determine duration of therapy

GP initiation of isotretinoin

- When criteria fulfilled
 - Moderate or persistent acne
 - Failure or long duration of standard therapy
 - GP self-assesses as adequately trained
 - Use decision support tool if you like
 - Males, or females-that-are-not-going-to-get-pregnant

Prior to treatment

- Prolonged consultation with patient
- Provide written material
- Discuss & arrange contraception for females
- Assess mental status & record in notes
- Arrange blood tests: CBC, LFT, lipids, beta-HCG
- Apply for Special Authority funding

Preliminary information to patient

Oratane®
isotretinoin

ACNE TREATMENT PROGRAMME
INFORMATION

douglas

ACNE TREATMENT

Acne, even severe acne, can be treated. Your doctor might have advised you to consider using Oratane (isotretinoin). If other treatments such as antibiotics aren't helping you, Oratane may even help prevent scarring from acne. It works by reducing the amount of oil that your skin produces. This then leads to a reduction of bacteria and a reduction of inflammation and skin associated with acne. You won't notice immediate changes on Oratane. The treatment usually works within about 20 weeks and as you can see in the photos below, the changes are significant. Oratane comes in a 1mg percentage of capsules. There will be some side effects - skin dryness is common. These side effects are what Oratane is working.

Because Oratane can affect an unborn baby, it is vital that you are not pregnant before starting, during and for one month after stopping treatment.

THINGS YOU SHOULD KNOW ABOUT ACNE

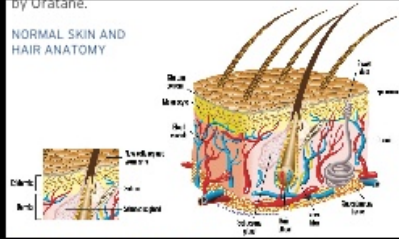
Acne is a common skin condition. It's made of blackheads, whiteheads, red spots and sometimes deeper so-called cysts which are called nodules or cysts.

Acne affects most people in their teenage years - some worse than others - and for some, the problem continues on into adulthood.

WHAT CAUSES ACNE?

Acne isn't the result of dirty skin and it isn't only a teenage problem. There isn't any evidence that sunbathing causes it, or following a diet on its own probably won't clear your acne. Acne is caused by excess sebum building up and a narrowing of the duct that these natural oils flow from. A 'plug' can then form which blocks pores. Acne is an easily treatable skin disorder and it can be cured by Oratane.

NORMAL SKIN AND HAIR ANATOMY



HOW ORATANE WORKS

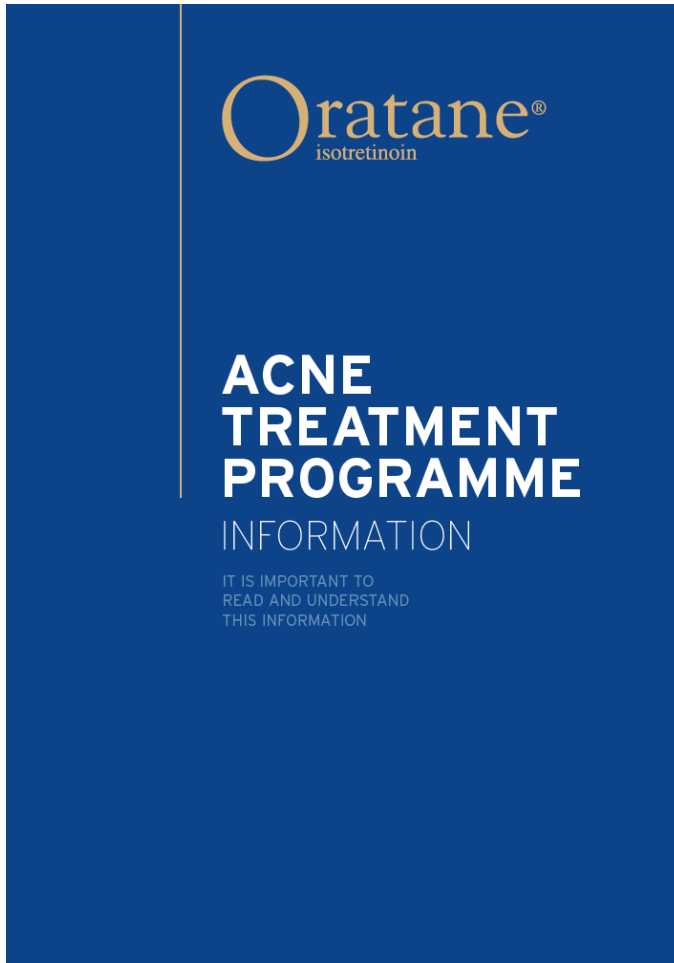
Oratane works by reducing the amount of oily substances excreted by the oil-secreting glands in your skin and by unblocking the pores. This reduces the amount of bacteria in the skin. These bacteria are the cause of the 'pus' and inflammation found with acne. Oratane may also help to reduce the inflammation of the skin.



BEFORE ORATANE DURING ORATANE AFTER ORATANE

<http://www.oratane.co.nz/>

More information



The image shows a blue leaflet for Oratane isotretinoin. At the top, the Oratane logo is in gold, with 'isotretinoin' in white below it. The main title 'ACNE TREATMENT PROGRAMME' is in large white capital letters, followed by 'INFORMATION' in smaller white capital letters. At the bottom, in small white capital letters, it says 'IT IS IMPORTANT TO READ AND UNDERSTAND THIS INFORMATION'.



FACE AND BODY MOISTURISERS



QV CREAM



QV LOTION



DRY NOSE

Face Moisturisers

Using a moisturiser on your face regularly will help keep the dryness that may be seen with Oratane treatment under control. The best type of moisturiser is an oil free face moisturiser for sensitive skin, you should avoid greasy moisturisers. Products you could try are: QV Lotion, Clinique Oil-Free Moisturiser, Hamilton Dry Skin Treatment and Avene Skin Recovery Cream.

Body Moisturisers

Body moisturisers should not be used on the face, unless they are also included in the Face Moisturisers section. To keep your skin in good condition you should use a moisturising lotion on your whole body, even if you don't seem to have any dryness, prevention is always better than cure. For extremely dry areas use a cream, rather than a lotion. Products you could try are: QV Skin Lotion, QV Cream, Hydraderm Lotion, Vaseline Intensive Care Lotion, Hamilton Dry Skin Treatment and Innova Sensitivity Soothing Moisture Lotion.

Dry lips

Your lips are particularly sensitive to the drying effects of Oratane. This makes it important to look after them well. This can be achieved very simply by applying a lip balm regularly.

By applying a lip balm every one to two hours you can prevent your lips from becoming dry and cracked. Make sure you also pay attention to the corners of your mouth, this area is prone to cracking. A lip balm that contains a sunscreen is best. You should carry a tube of lip balm with you during the day. You should see your local doctor if your lips become very cracked or begin bleeding.

Products you could try are:

QV Lip Balm, Vaseline Lip Therapy, Lip Sed, Blistex, Hamilton Lipz Lip Ointment and Avene Lip Balm with Cold Cream.

Dry Nose

The inside of your nose can also become dry while you are taking Oratane. If this becomes severe it can result in nosebleeds. To keep the inside of your nose moist you should apply a small amount of petroleum jelly a few times a day using a cotton bud. If you suffer from persistent nose bleeds or your nose bleeds are difficult to stop, you will need to see your pharmacist or your doctor. Severe nose bleeds can be treated with prescription products.

Dry Eyes

If you find that your eyes feel dry or sore then you may need to use eyedrops to keep them moist. Dry eyes can be a particular problem for people who wear contact lenses or people who work in air-conditioned areas. If you wear contact lenses you may find that you

<http://www.oratane.co.nz/>

Obtain consent

- Discuss birth control
- Discuss depression

CONFIRMATION OF RECEIPT OF INFORMATION ON THE TREATMENT OF SEVERE ACNE WITH ORATANE® (isotretinoin)

Female Patients

I understand that I must not be pregnant in order to start this medicine. I understand that I must not become pregnant while being treated with Oratane and for **one month** after the end of Oratane treatment.

I understand the risks associated with becoming pregnant while on Oratane as explained by my dermatologist. I am aware that significant harm may be caused to my unborn baby should it be exposed to Oratane during pregnancy.

As a precaution I agree to undergo a pregnancy test if necessary and have my doctor confirm that I am not pregnant immediately before starting treatment with Oratane.

I am aware that methods to avoid pregnancy are absolutely essential during my treatment on Oratane. The safest option is an oral contraceptive plus a barrier. If there is any risk that pregnancy may have occurred, I agree to consult my specialist or GP to discuss the need for emergency contraception.

I agree to avoid the possibility of pregnancy for **one month before** commencing treatment with Oratane, during the whole period of treatment and for **one month after** completion of treatment. Should I become pregnant, I agree to inform my doctor immediately.

All Patients

I understand that I must not give Oratane to any other person.

I understand that while Oratane may help my skin, it may cause a number of side effects that have been explained to me.

I understand that this medicine may give rise to mood changes. I agree to inform my doctor immediately if I start to feel unhappy or depressed on this medicine.

I confirm that I have been fully informed of the above by:

Doctor: _____

Patient Name: _____

Patient or Guardian Signature: _____

Date of Birth: ____ / ____ / ____ Today's Date: ____ / ____ / ____

Address: _____

<http://www.oratane.co.nz/>

Don't use isotretinoin if:

- Pregnancy test positive
- Unmanaged depression
- Unexpected systemic disease
 - E.g. infectious mononucleosis
- Hypertriglyceridaemia >6 mmol/L
- Uncontrolled eczema / dry eyes / nosebleeds etc



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Prescriber Update Articles

Avoiding Teratogenicity with Isotretinoin

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The teratogenicity of isotretinoin is well documented. The first New Zealand case of embryopathy was recently reported to CARM. This is a timely reminder that effective contraception is recommended for all women of childbearing age for whom isotretinoin is a treatment option. It is also important to exclude pregnancy prior to starting isotretinoin, and for women to continue contraception for one month after stopping isotretinoin.

Isotretinoin known to cause severe foetal malformations

First NZ report of isotretinoin associated embryopathy

High incidence of severe malformations seen in US study

Implement precautions to avoid pregnancy in women using isotretinoin

References

The teratogenic risks of isotretinoin

If pregnancy occurs either during treatment with isotretinoin or in the month following the end of treatment with isotretinoin there is a great risk of very severe and serious malformation of the foetus.

The foetal malformations associated with exposure to isotretinoin include:

- central nervous system abnormalities (hydrocephalus, cerebellar malformation/ abnormalities, microcephaly)
- facial dysmorphism
- cleft palate
- external ear abnormalities (absence of external ear, small or absent external auditory canals)
- eye abnormalities (microphthalmia)
- cardiovascular abnormalities (conotruncal malformations such as tetralogy of Fallot, transposition of great vessels, septal defects)
- thymus gland abnormality and parathyroid gland abnormalities.

There is also an increased incidence of spontaneous abortion.

Psychiatric side-effects

Depression, aggravation of existing depression, aggressive tendencies, anxiety, and changes in mood have been reported rarely in patients taking isotretinoin (i.e. occurring in one or more of every 10,000 patients, but in fewer than one in every 1,000 patients); abnormal behaviour, psychotic disorder, suicidal ideation, suicide attempt, and suicide have been reported very rarely (ie, in one in every 10,000 patients or fewer).

When to follow up?

- One to three months
- Consider:
 - Patient's character
 - Acne severity
 - Comorbidities
- Always provide a phone number and see patient face to face if there are any concerns
- Train nurse to field calls

What dose?

- 0.1 to 1 mg/kg/day
 - 5 – 60 mg/day for 60kg adult
- Low doses are often effective
 - Start 10-20 mg/day and build up if required
 - Tolerance varies
- Higher doses advocated by many
 - Quicker results
 - Higher long term cure rates
 - Reduced pregnancy-risk

For how long?

- 100-150 mg/kg
 - 125 days at 1 mg/kg
 - 1250 days at 0.1 mg/kg
 - 20-30% relapse
- Individualise
 - Until clearance + some
 - Stop and start again if necessary
 - Long term in adult acne



Additional treatment

- Contraception
- Antibiotics if very inflammatory
 - Not tetracyclines
 - Erythromycin / trimethoprim
- Emollients

Acne getting better

- Great !
 - Keep dose same
 - Reduce dose or frequency
 - Eventually stop ...



Acne unchanged

- Why?
 - Noncompliance
 - Underlying cause
- Keep dose same: patience!
- Increase dose: quicker response



Acne getting worse

- Why?
 - Underlying cause
 - Herxheimer response
- Reduce dose or stop
- Add antibiotic
- Call for help
- May require systemic steroids



Dry or cracked lips

- Lip balm ++
- Sunscreen
- Don't lick
- Topical antibiotic to angles of mouth & nostrils: 7-day course



Dry or bleeding nose

- Vaseline
- Topical antibiotic: 7-day course

Dry or watery eyes

- Wrap-around sunglasses outdoors
- Reduce wearing contact lenses
- Artificial tears
 - Ocular lubricant eg Poly-Tears™



Dry and sensitive skin

- Soapless cleanser
- Regular emollient at least bd
- Careful sun protection
- Don't wax
- For retinoid dermatitis:
mild topical steroid for a
few days



Muscles, joints and fatigue

- Mild – reassure
- Moderate – reduce dose
- Sometimes, reduce exercise

Headache

- Mild: drink more fluids; may take paracetamol
- Moderate: reduce dose
- Severe: examine for papilloedema& stop isotretinoin
- Ensure patient is not taking additional vitamin A or tetracycline

Contraception

- Combined ocp or IM progesterone + condoms
 - IUD, Mirena + condoms
 - Vasectomy / tubal ligation
 - Abstention
-
- Not minipill (progesterone-only) reduced efficacy

Depression

- Grumpiness & tiredness common in isotretinoin patients
- Depression usually pre-existing or due to other causes
- Rarely due to isotretinoin but take a good history
- Stop isotretinoin if any doubt – try again later
- Treat depression as you would normally

What to do if ... diabetic

- Blood tests
 - Watch out for hypertriglyceridaemia
 - Monitor blood sugar as usual

What to do if ... hyperlipidaemia

- Isotretinoin increases triglyceride > LDL cholesterol
- Monitor if pretx levels elevated or family history or risk factors
- Main risk is pancreatitis
- Reduce intake of carbohydrates e.g. alcohol, pop, fruit juices
- Keep dose of isotretinoin low

What to do if ... bone disease

- Isotretinoin has been associated with both osteoporosis and DISH
- Does not appear a problem with standard courses
- Most reports are in high dose use longtermeg 100mg daily for 2 years
- Consider other risk factors
 - Age, gender
 - Smoking, alcohol
 - Exercise or lack of it
 - Hormonal status etc

What to do if ... eczema

- Treat eczema first
 - No soap
 - Thick emollients
 - Topical steroids
 - Antibiotic if necessary
- Warn patient will require more emollient and skin will be more sensitive
- Eczema is sometimes **BETTER** on isotretinoin because of its immunosuppressive action



What to do if ... impetigo

- Topical antiseptic if mild and localised
- Topical antibiotic if moderate and localised
- Flucloxacillin if required



What to do if ... paronychia

- Trauma: advice re
 - Footwear
 - Nail cutting
- Staph. infection
 - Antisepsis
 - Short course antibiotic
- Inflammation
 - Topical steroid
- Delay or avoid surgery until off isotretinoin for several months
- Stop isotretinoin for several months if severe problem



What to do if ... outdoor worker

- Dress up
- Sunscreen on exposed areas



What to do if ... competitive sports

- Consider:
 - Sun exposure
 - Muscles / joints
 - Fatigue
 - Grazes



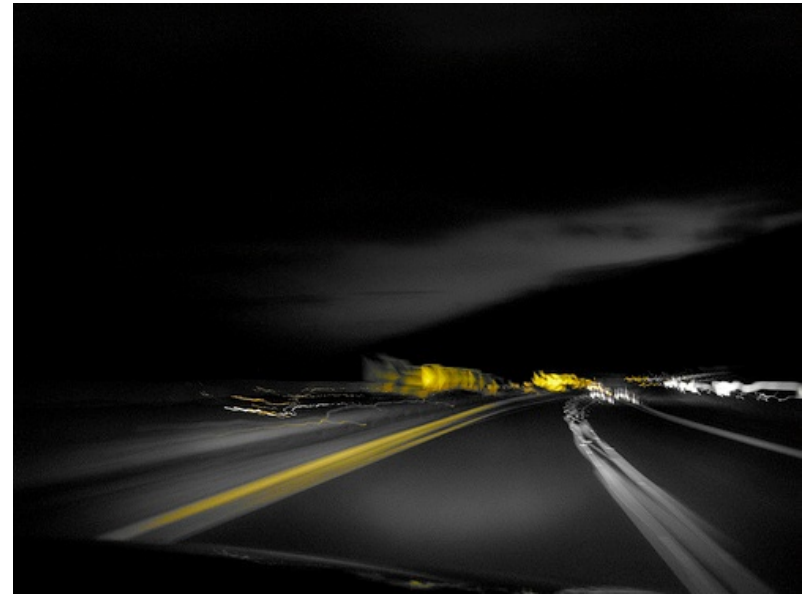
What to do if ... xsEtOH

- Encourage reduction in intake
- Watch for:
 - Hypertriglyceridaemia
 - Abnormal LFT



What to do if ... drives at night

- Warn that some individuals lose night vision as retinoids interfere with rods
- Some people have to make a choice: isotretinoin or driving



What to do if ... impending surgery

- Atrophied sebaceous glands delays healing and risks bad scars
- Avoid elective facial procedures for 6 months after isotretinoin
 - Laser
 - Dermabrasion
- Stop for a week or two for essential skin surgery
- Stop for a week or two for any surgical procedure



What to do if ... no visible acne

- Dysmorphophobic acne?
- Microcomedones?
- Try topical retinoid
- Isotretinoin can be effective

Patient dependence

- Quite common!
- Slowly, slowly reduce dose and frequency of treatment
- Review regularly and discuss options e.g. for topical tx

Relapse

- Start again
- Consider options
- Most patients will choose another course of isotretinoin but some prefer topicals and a few want antibiotics

Long term treatment

- Required for
 - Adult acne – mainly women
 - Seborrhoea
 - Follicular occlusion syndrome
 - Dysmorphophobia
- Adjust dose to minimum
- Re-evaluate every 6 months
 - Blood tests if risk factors for complications

For further information

- BMJ Learning
- BPAC
- Decision Support tool
- DermNetNZ
- A doctor's guide to prescribing
- Get to know your local dermatologist



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