



ISOTRETINOIN

What are the aims of this leaflet?

This leaflet has been written to help you understand more about isotretinoin. It tells you what it is, how it works, how it is used to treat skin conditions, and where you can find out more about it.

What is isotretinoin and how does it work?

Isotretinoin is a member of a group of drugs, closely related to vitamin A, called retinoids. Isotretinoin is the generic name of a drug marketed by a number of companies, but the original brand name was Roaccutane. It works in a variety of ways, targeting several of the factors that cause acne and other skin conditions including the production of sebum (an oily substance produced by the skin) and the production of keratin (outer scales of skin) that block the pores of the hair follicle and cause acne.

What skin conditions are treated with isotretinoin?

Isotretinoin is licensed and commonly used to treat moderate and severe acne, often where there is risk of scarring. Your dermatologist may occasionally use isotretinoin to treat other skin conditions such as [hidradenitis suppurativa](#) and [rosacea](#). In the United Kingdom isotretinoin may only be prescribed if you are under the care of a consultant dermatologist.

Will isotretinoin cure my acne?

A large proportion of patients (about 9 out of 10) see a significant improvement in their acne with a single 16 to 24 week course of isotretinoin, although during the first few weeks of treatment the acne may worsen before it starts to improve.

A small number of patients continue to have milder (although improved) acne following isotretinoin that can be controlled with conventional therapies, such as antibiotics. Others may relapse after stopping treatment with isotretinoin, and occasionally, a prolonged or second course of treatment is required.

What dose should I take and for how long?

Your dermatologist will calculate the amount of isotretinoin you need according to your body weight and decide on an appropriate starting dose. At future appointments the dose of isotretinoin may be changed depending on how well you are coping with the side effects and responding to the medication. Most patients take between 20 mg and 80 mg of isotretinoin each day, and a course commonly lasts between 16 and 24 weeks. With doses in the lower end of this range, which are often better tolerated, a course may last longer than 24 weeks. Your acne may continue to improve for up to 8 weeks after treatment.

How should I take isotretinoin?

As isotretinoin is best absorbed into the body with food containing some dietary fat, it should ideally be taken after a meal or a snack with milk rather than on an empty stomach. The capsules need to be swallowed whole and should not be crushed or split open. Keep the capsules in a cool (5 to 25°C) dark place away from children.

What are the common side effects of isotretinoin?

In general, dryness of the skin, lips, and eyes is the most common side effect. Using a non-comedogenic moisturiser (one that does not block the skin pores) and a lip balm regularly will help to prevent these symptoms. An increased risk of skin infections accompanies the skin becoming dry and cracked. Nosebleeds may occur if the inside of the nose becomes very dry. Dry eyes may interfere with the wearing of contact lenses and may be helped by using artificial tears. The skin may also peel and become fragile, with wounds taking longer to heal. Whilst taking isotretinoin, and for six months afterwards, your skin will be more delicate than usual; waxing, epilation, dermabrasion and laser treatment should be avoided. Shaving is normally tolerated, but use of a moisturiser afterwards is advisable.

Isotretinoin may increase your skin's sensitivity to the sun. You should therefore avoid direct sun exposure whilst taking this medication. Where

necessary a sun-protection product with a high protection factor of at least SPF 30 should be used. You should also avoid the use of sun beds.

Muscles and joints may ache especially after exercise. Temporary hair thinning may occasionally occur. Isotretinoin can affect your vision, in particular the ability to see at night, and caution is required in people whose job requires good night vision, such as drivers and those who operate heavy machinery. If you develop difficulties seeing at night or in dark situations you should avoid driving and/or operating heavy machinery. Airline pilots will not be able to continue their job while on isotretinoin and are advised to discuss this with their employer before starting the medication, and check with current Civil Aviation guidelines. These vision changes may be permanent in extremely rare circumstances.

Increased fat levels in the blood, and mild liver inflammation, can occur but are usually not of clinical significance; these will be monitored by blood tests during the course of treatment. If you have had problems with your liver or kidneys, or suffer from high cholesterol or diabetes, you should discuss this with your doctor prior to starting the medication.

Peanut or soya allergy

Isotretinoin contains soya oil. Occasionally, patients with soya allergy might react to the trace levels of soya proteins in soya oil. Exceptionally rarely, patients with peanut allergy might have a cross reaction to soya proteins in soya oil. You should inform your doctor and pharmacist if you think you may have an allergy to soya or peanut.

What are the rare side effects of isotretinoin?

A number of more serious side effects may occur although these are fortunately rare. Isotretinoin can lead to changes in mood and/or behaviour and less commonly, unusual experiences including thoughts of self-harm and suicide. There have also been reports of patients attempting suicide. If you have ever had low mood, suicidal ideas or any other mental health problem, please discuss this with your doctor before starting treatment. If you have a history of depression your dermatologist may ask a psychiatrist to see you before starting isotretinoin to determine if it is safe for you to take. **If you or your friends/relatives feel that your mood or behaviour is changing, or if you start having thoughts of self-harm whilst taking isotretinoin, please inform your doctor and stop taking it immediately. Your doctor will then discuss it with you and advise if it is safe to take in the future.**

Rarely, inflammation of the liver or pancreas may occur. Very rarely, increased pressure in the brain may present with morning headaches and disturbance of vision.

If you do suffer from a side effect then stopping or reducing the dose of isotretinoin may resolve the problem. Please talk to your doctor or nurse before making any changes to your medication.

The list of side effects is not exhaustive, and if you do develop any new problems while taking isotretinoin please inform your doctor or nurse.

May I drink alcohol whilst taking isotretinoin?

Ideally alcohol should be avoided completely, as this can cause inflammation of the liver.

Can I take other medications at the same time as isotretinoin?

Most drugs can be taken safely with isotretinoin but some medications may interact. It is important that you tell your doctor and pharmacist what you are currently taking before taking any new prescription or over-the-counter medications.

Medications to avoid while taking isotretinoin include:

- Tetracycline antibiotics
- Methotrexate

This is not a complete list and it is important that you always inform your doctor and pharmacist that you are taking isotretinoin, and read the in-pack leaflet.

Vitamin supplements containing vitamin A should be avoided during a course of isotretinoin.

Are there any other precautions whilst taking isotretinoin?

You must never share your tablets, especially with women. Do not donate blood whilst taking isotretinoin and for a month afterwards in case the blood is given to a pregnant woman.

There has been no known adverse effect on the pregnancy if a man taking isotretinoin fathers a child. However, as isotretinoin is present in semen, it may be a sensible precaution to use a condom to avoid transmission of any of the drug to females.

Women should not breast feed while taking isotretinoin.

Why is there concern about women taking isotretinoin and pregnancy?

If a pregnant woman takes isotretinoin there is a high risk that the unborn baby will be harmed. There is an increased risk of miscarriage and babies may have severe and serious defects (such as abnormal appearance or intellectual disability). For this reason:

- Isotretinoin should not be taken during pregnancy.
- You must not become pregnant whilst taking isotretinoin, or for at least one month after stopping isotretinoin.
- You should not breast feed whilst taking isotretinoin, or for one month afterwards.
- If you do become pregnant, or suspect that you may be pregnant, you must stop the medication immediately and contact your doctor, so you may be referred to a specialist pregnancy clinic.

What is the Pregnancy Prevention Programme?

All women considered to be able to conceive should be entered into the Pregnancy Prevention Programme whilst taking their course of isotretinoin, in order to minimise the risk of pregnancy.

- Before starting isotretinoin you must use at least one, and preferably two, forms of adequate contraception for at least one month before starting treatment. It is necessary to discuss general aspects of contraception with your doctor or nurse.
- Usually one form of contraception will need to be a barrier method such as condoms or a cap.
- Contraceptive pills are considered to be effective. Certain antibiotics (e.g. amoxicillin) and herbal products (e.g. St John's Wort) can interfere with hormonal contraceptives ('The Pill') making them less effective.
- You will be given your first prescription for isotretinoin after having a negative pregnancy test at the clinic.
- Ideally you should start treatment on day 2 or 3 of your menstrual cycle.

- Each month you will attend the clinic for a pregnancy test and you will have a final pregnancy test 5 weeks after finishing treatment.
- You will only be supplied with 30 days of treatment on each visit following a negative pregnancy test.
- You must collect your prescription for isotretinoin from the pharmacy within 7 days of it being signed by your doctor.
- Contraception needs to be continued after treatment is stopped, for a further month.
- Once you have completed your course of isotretinoin and been advised to stop isotretinoin by your doctor, you should not take any further capsules. Any capsules left over should be returned to the hospital or your pharmacist.

Do all women have to enter the Pregnancy Prevention Programme?

Women who are unable to become pregnant due to medical reasons, or who have been sterilised, may be excluded from the Pregnancy Prevention Programme. In exceptional circumstances, females capable of becoming pregnant but who are not sexually active may be exempted from the Pregnancy Prevention Programme.

Will isotretinoin affect future pregnancies?

Isotretinoin does not affect fertility. One month after finishing a course of isotretinoin, you may get pregnant with no additional risk to the unborn baby.

Where can I find out more about isotretinoin?

If you would like any further information about isotretinoin, or if you have any concerns about your treatment, you should discuss this with your doctor or pharmacist. This information sheet does not list all the side effects this drug can cause. For full details, please see the drug information leaflet that comes with your medicine. Your doctor will assess your medical circumstances and draw your attention to side effects that may be relevant in your particular case.

Web links to detailed leaflets:

<http://www.dermnetnz.org/treatments/isotretinoin.html>

<http://www.drugs.com/mtm/isotretinoin.html>

<http://www.medicines.org.uk/emc/medicine/21511/SPC>

For details of source materials used please contact the Clinical Standards Unit (clinicalstandards@bad.org.uk).

This leaflet aims to provide accurate information about the subject and is a consensus of the views held by representatives of the British Association of Dermatologists: individual patient circumstances may differ, which might alter both the advice and course of therapy given to you by your doctor.

This leaflet has been assessed for readability by the British Association of Dermatologists' Patient Information Lay Review Panel

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