



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 and where you can find out more about it.

What is isotretinoin and how does it work?

Isotretinoin (brand name Roaccutane) belongs to a group of drugs called retinoids, which are closely related to vitamin A. It works in a variety of ways, targeting different factors that cause acne 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.

What skin conditions are treated with isotretinoin?

Isotretinoin is licensed to treat 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 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 further 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 side effects and your response 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. The benefits of isotretinoin may continue in the skin for several years after treatment.

How should I take isotretinoin?

As isotretinoin is better absorbed into the body with food containing some fat, it is best to take the medication after a meal. 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.

Caution for patients of child-bearing potential

Patients must not take isotretinoin in pregnancy. If a person becomes pregnant whilst taking isotretinoin or 4 weeks after they finish the course, there is a high risk that the baby will be harmed with severe and serious defects (such as abnormal appearance or intellectual disability) and an increased risk of miscarriage.

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. A termination of pregnancy will be recommended. You should not breast feed while taking isotretinoin and for a month after completing treatment.

Please see below for more information on the Pregnancy Prevention Programme.

What is the Pregnancy Prevention Programme?

All women with child-bearing potential should be entered into the Pregnancy Prevention Programme whilst taking their course of isotretinoin, in order to

minimise the risk of pregnancy. There are rules that the government body, the Medicines and Healthcare products Regulatory Agency, has produced which doctors and pharmacists must follow:

- Before starting isotretinoin you must use at least one, and preferably two, forms of effective contraception for at least one month before starting treatment. It is necessary to discuss general aspects of contraception with your doctor or nurse.
- Combined 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.
- However, oral progestogen-only contraceptives ("the mini pill") are NOT considered effective on their own as a contraceptive, but can be used in conjunction with other contraceptive methods.
- Barrier methods, such as condoms and caps, should not be used alone, but can be used in conjunction with other contraceptive methods.
- 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.

Do all women have to enter the Pregnancy Prevention Programme?

Women who are unable to become pregnant due to medical reasons, or have been sterilised, or had a hysterectomy, or had both ovaries surgically removed, or postmenopausal (defined as more than a year since last menstrual period) 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.

There has been no known adverse effect on the pregnancy if a man taking isotretinoin fathers a child even though small amounts of isotretinoin is found in semen.

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. Extremely rarely, patients with peanut allergy might also have a reaction to the 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 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 lip balm regularly will help. In more severe cases, this can turn into eczema and may require additional treatment. Nosebleeds may occur if the inside of the nose becomes very dry. Dry eyes may make the wearing of contact lenses a little uncomfortable and may be helped by using artificial tears eye drops available over the counter.

As a result of the skin becoming dry and cracked, the risk of skin infection is increased. Wounds may also take longer to heal and the skin may feel fragile and peel with friction. Whilst taking isotretinoin, and for six months afterwards, your skin will be more delicate than usual; hair removal using waxing, epilation, dermabrasion, or laser treatment, as well as tattoos and piercings 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 rarely affect your vision, in particular the ability to see at night (less than 1 in 10,000 chance). If you develop difficulties seeing at night or in dark situations you should avoid driving and/or operating heavy machinery. Patients whose jobs may be impacted by this, such as drivers, airline pilots, people in the military, and those who operate heavy machinery, are advised to discuss this with their employer before starting the medication, and check with current Civil Aviation guidelines. These night vision changes may be permanent in extremely rare circumstances.

Isotretinoin may sometimes cause an increase in the levels of fats in your blood (which can lead to inflammation of the pancreas), or inflammation of the liver. Blood tests will be requested during treatment to monitor any potential side-effects.

What are the rare side effects of isotretinoin?

A number of more serious side effects may occur although these are rare. Isotretinoin can lead to changes in mood and/or behaviour (between 1 in 1,000 and 1 in 10,000 chance) and less commonly, unusual experiences including thoughts of self-harm and suicide. There have also been reports of patients attempting suicide (less than 1 in 10,000 chance). If you have ever had low mood, suicidal ideas or any other mental health problem, please discuss this with your dermatologist 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 dermatologist will then discuss it with you and advise if it is safe to take in the future.**

A very rare side effect is raised pressure in the brain (less than 1 in 10,000 chance), this causes severe headache, nausea, vomiting and blurred vision.

Sexual side effects, such as erectile dysfunction, vaginal dryness, and decreased libido, may also occur; these are understood to be rare but may persist despite completing the course of treatment.

There have been few rare cases of patients developing inflammatory bowel disease such as, Crohn's disease and ulcerative colitis, during or after treatment with isotretinoin. Although it has not been proved that isotretinoin causes this, please stop taking your medication immediately if you develop bloody diarrhoea and see your GP on the same day or attend the nearest

Accident and Emergency department depending on the severity of your symptoms and how you feel.

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

Are there any other precautions whilst taking isotretinoin?

You must never share your tablets with other people. You cannot donate blood when taking isotretinoin and for at least one month after stopping the medication in case the blood is given to a pregnant woman.

Can I drink alcohol whilst taking isotretinoin?

Yes, but not to excess as alcohol can also cause inflammation of the liver. You should not exceed the government recommended guidelines for alcohol consumption (no more than 14 units per week).

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 (including herbal remedies).

Medications to avoid while taking isotretinoin include:

- Tetracycline antibiotics
- Methotrexate
- Vitamin A supplements (including multi-vitamins containing vitamin A)

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.

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.

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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