



ISOTRETINOIN - FEMALE

Please note that this information leaflet is for women, there is a separate information leaflet for men.

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 such as Beacon and Ranbaxy, but the original brand name was Roaccutane, marketed by Roche. It works in a variety of ways, targeting several of the factors that cause acne and other skin conditions including production of sebum (an oily substance produced by the skin) and the bacteria that contribute to acne.

What skin conditions are treated with isotretinoin?

Isotretinoin is licensed and most commonly used to treat severe acne, often where there is scarring and pigmentation. 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 90%) 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 tolerating and responding to the medication. Most patients take between 20mg and 80mg of isotretinoin each day, and a course commonly lasts between 16 and 24 weeks. With doses in the lower part of this range, which are often better tolerated, a course may last much 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 cannot 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 the side effects of isotretinoin are mild and settle later in the course of treatment. Dryness of the skin, lips, eyes and throat is common. An increased risk of skin infections accompanies the skin becoming dry and cracked, and nosebleeds may occur if the inside of the nose becomes very dry. Using a moisturiser and lip balm regularly will help to prevent these symptoms. Dry eyes may interfere with the wearing of contact lenses. 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.

There is an increased risk of sunburn and you should use a sunscreen when appropriate. Muscles and joints may ache especially after exercise.

Temporary hair thinning may occasionally occur. Isotretinoin can affect night vision and it should be used with care in people whose job requires good night vision, such as airline pilots and drivers.

Increased fat levels in the blood, and mild liver inflammation, are common and not usually 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.

Some brands of isotretinoin contain soya (e.g. Beacon brand) and peanut oil (e.g. Roaccutane (Roche brand)), and you should inform your doctor if you think you may have an allergy to these.

What are the rare side effects of isotretinoin?

A number of more serious side effects may occur although these are fortunately rare. There have been reports of isotretinoin leading to mood change although the risk of this is small. Rates of depression in acne patients range from 1 to 11% in different trials, and are the same whether patients are taking antibiotics or isotretinoin. However, if you have any prior history of depression, or other mental illness, please discuss this with your doctor before starting treatment. If you or your relatives feel that your mood is changing whilst taking isotretinoin, please inform your doctor.

Rarely, inflammation of the liver or pancreas may be seen. 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.

May I drink alcohol whilst taking isotretinoin?

Ideally avoid alcohol completely, although small amounts of alcohol (up to 1 unit per day) are unlikely to cause any harm.

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.

Drugs that adversely interact with isotretinoin include:

- Tetracycline antibiotics (only if taken at the same time as isotretinoin)
- Methotrexate

This is not an exhaustive list and it is important that you always inform your doctor and pharmacist that you are taking isotretinoin.

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 other women. Do not donate blood whilst taking isotretinoin in case the blood is given to a pregnant woman.

Why is there concern about women taking isotretinoin and pregnancy?

If a pregnant woman is exposed to isotretinoin there is a high risk that the unborn baby will be harmed, leading to severe and serious defects (such as abnormal appearance or mental handicap) or miscarriage. 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 abnormality clinic.

What is the Pregnancy Prevention Programme?

All women considered to be at risk of conceiving will 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. The progesterone-only pill (The Minipill) is not considered effective contraception. 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.

Do all women have to enter the Pregnancy Prevention Programme?

Women who are not sexually active, or who are unable to become pregnant due to medical reasons, or who have been sterilised, may be excluded 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:

European Dermatology Forum Guidelines on Acne

http://www.euroderm.org/edf/index.php?option=com_content&view=article&id=50&Itemid=56

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: its contents, however, may occasionally differ from the advice given to you by your doctor.

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

**BRITISH ASSOCIATION OF DERMATOLOGISTS
PATIENT INFORMATION LEAFLET
PRODUCED NOVEMBER 2011
REVIEW DATE NOVEMBER 2014**