



## WHAT ARE THE AIMS OF THIS PATIENT GUIDE?

This patient guide is to help you understand more about isotretinoin so you can consider whether it is the right treatment for you.

It explains the benefits of treatment, possible side effects and why isotretinoin must not be taken in pregnancy.

It discusses possible mental health and sexual function effects which were raised in the April 2023 [report](#) by the Commission on Human Medicines' Isotretinoin Expert Working Group.

There is a separate information leaflet about isotretinoin especially written for young people - Medicines for Children 'Oral isotretinoin guide for young people' (<https://bit.ly/isog4yp>). We recommend you look at this if you are under 18 and considering isotretinoin treatment.

## WHAT IS ISOTRETINOIN AND HOW DOES IT WORK?

Isotretinoin is a retinoid drug which is part of the same family as Vitamin A. It may be known by brand names that include Roaccutane, Accutane (USA) and Reticutan. It reduces the production of sebum – an oily substance made by the skin. It also reduces the production of keratin – the outer layer of skin, which can block pores.

## WHAT IS ISOTRETINOIN USED FOR?

Isotretinoin is licensed (approved by drug regulators in the UK) to treat severe [acne](#) in people over 12 years when other treatments have not worked or if there is a risk of permanent scarring. Dermatology healthcare professionals may occasionally recommend isotretinoin outside of its licensed use. They should tell you it is being used in this way and discuss with you whether you still want to take it.

## HOW CAN I DECIDE WHETHER I WANT TO TAKE ISOTRETINOIN?

You should read this patient guide carefully and ask any questions you have before deciding whether you want to take isotretinoin. You should give your dermatology healthcare professional all the information they need about treatments you have already tried, how the [acne](#) affects you, possible plans for pregnancy, other medical problems and any history of mental health problems. This will help your dermatology healthcare professional decide with you whether isotretinoin is the best treatment for you.

## WHAT SHOULD I EXPECT FROM ISOTRETINOIN?

Most people find isotretinoin helps their [acne](#) and, for many, can clear their skin. There is a possibility that your acne might get worse for a few days or weeks before it starts to get better. Most people find their acne stays better for several years after they finish isotretinoin.

## HOW IS MY DOSE AND TREATMENT LENGTH DECIDED?

Your dermatology healthcare professional will work out your initial dose according to your weight and after discussion about possible side effects. Your dose will be reviewed at each follow up appointment. Treatment is usually continued until your [acne](#) has been clear for a few weeks. Some specialists may treat to a fixed total amount (generally 120-150 mg/kg). A course of treatment is generally around 24 weeks (6 months) but may be longer if low doses are used.

## HOW SHOULD I TAKE ISOTRETINOIN?

Isotretinoin is usually taken once a day. It works best if it is taken with a main meal or a drink which contains some fat (for example,

milk, butter or oil) because this helps it to be taken into the body.

- Swallow the whole capsules. Do not crush or split them.
- Keep the capsules in a cool (below 25°C), dark place and away from children.

If you have swallowing difficulties, your specialist can advise on the best way to take it.

### WHAT IMPORTANT THINGS DO I NEED TO KNOW ABOUT ISOTRETINOIN?

- Isotretinoin must not be taken in pregnancy or if you are trying to get pregnant as this could cause serious harm to the baby (see section below for people with child-bearing potential).
- Isotretinoin capsules must never be shared with other people.
- You must not donate blood whilst taking isotretinoin and for at least 1 month after stopping the medication. This is because the blood may be given to a pregnant person.
- Isotretinoin and alcohol can affect the liver so you should not drink much alcohol while you are taking isotretinoin. Do not drink more than the recommended maximum 14 units per week of alcohol – see NHS website for more details.
- Isotretinoin capsules contain highly processed soya. Please discuss with your dermatology specialist if you are allergic to peanut or soya and see the British Association of Dermatologists position statement on isotretinoin and soya allergy ([www.bad.org.uk/pils/isotretinoin-and-soya-allergy](http://www.bad.org.uk/pils/isotretinoin-and-soya-allergy)).
- It is best to avoid treatments such as waxing, epilation, or dermabrasion, as well as tattoos and piercings during treatment and for up to 6 months afterwards. They could cause scarring, skin irritation, or rarely, changes in the colour of your skin.

- People whose jobs require them to see at night (such as drivers, airline pilots, people in the military and those who operate heavy machinery) are advised to have a discussion with their employer before starting isotretinoin. This is because it can reduce night vision.

### CAN I TAKE OTHER MEDICATIONS AT THE SAME TIME AS ISOTRETINOIN?

Most medicines are safe to take during isotretinoin treatment. However, some medicines may not be. Medications to avoid while taking isotretinoin include:

- Tetracycline antibiotics (includes lymecycline and doxycycline).
- Vitamin A supplements (including multi-vitamins containing vitamin A).
- Some acne creams, due to a higher risk of irritation.

This is not a complete list, and it is important that you always inform your doctor and pharmacist that you are taking isotretinoin before taking any new prescriptions or over the counter medications and read the information leaflet in the packet.

(Read more <https://bit.ly/iso10mg>; <https://bit.ly/iso20mg>)

### SIDE EFFECTS

Oral isotretinoin may cause serious side effects. While these are rare, it is important that you understand the potential risks in order to make an informed decision about whether to take it.

#### *What are the common side effects of isotretinoin?*

- Dry lips (sometimes chapped or split).
- Dry skin, which may be more delicate than usual.
- Dry eyes.
- Increased skin sensitivity to the sun with more chance of getting sunburnt.
- Back pain, muscles and joints aches, especially after exercise.
- Changes in the blood tests which are monitored by your dermatology team.



These include mildly raised liver enzymes and changes in blood fat levels, which in healthy people are not usually serious.

- Headaches.

These side effects usually resolve a few weeks after stopping isotretinoin.

### *What can I do to help?*

- Use a non-greasy moisturiser designed for acne-prone skin, and a lip balm.
- To prevent skin irritation, you should avoid using exfoliating or anti-acne products.
- Use lubricating eye drops (non-prescription) for dry eyes, if needed. If contact lenses are uncomfortable you may need to wear glasses instead.
- Avoid too much sun. If you go out in the sun, protect your skin with clothing and wear a hat and sunglasses. Use sunscreen with a sun protection factor (SPF) of 30 or above. You must not use a sun lamp or sun beds.
- If you get muscle or joint pains, you are advised to cut down on intensive exercise and physical activity to avoid making it worse.
- Paracetamol or non-steroidal anti-inflammatory drugs (for example, ibuprofen) may be taken for muscle/joint pains or headaches.

### *What other possible side effects can occur?*

- Serious immediate allergic reaction with sudden rash, swelling of the lips, mouth or throat, and difficulty breathing or swallowing. Call 999 and take an antihistamine straight away, if available. Do not take any more isotretinoin.
- Sore or inflamed throat and nose and possible nose bleeds.
- Hair loss. This is usually only mild and temporary. Your hair should return to normal after the treatment ends.
- Vision problems, especially decreased night vision. If you develop difficulties seeing in dark conditions, you should avoid driving and/or operating heavy

machinery. In rare instances, vision problems and dry eyes have persisted after the end of isotretinoin treatment.

- Bowel (gut) problems. This may lead to feeling sick (nausea), being sick (vomiting) and/or diarrhoea (which might contain blood).
- Feeling weak or dizzy; having more frequent infections or getting bruising/bleeding.
- Inflammation of the liver. This can show as yellow skin or eyes and feeling tired.
- Raised pressure in the brain. This causes a lasting headache, along with feeling sick (nausea), being sick (vomiting) and a change in your eyesight including blurred vision.

Please read the information leaflet in the packet for more details of possible side effects.

If you are concerned that you have developed any serious side effects, you should stop taking isotretinoin straight away and contact your GP and dermatology team.

### **ISOTRETINOIN AND POTENTIAL MENTAL HEALTH PROBLEMS (PSYCHIATRIC SIDE EFFECTS)**

Isotretinoin has been associated with mental health problems in some people. The current published research does not give a clear answer as to whether isotretinoin is the cause of these mental health problems in some people.

We know that people with acne are more likely to have anxiety and depression than people without acne. This is because acne may affect self-confidence and make people distressed about the way they look.

Several studies have shown that isotretinoin can improve negative mood changes caused by acne.

However, there are some reported experiences of worsening mood or changes in behaviour, including anxiety, low mood, depression, agitation, aggression towards others, or a loss of contact with reality



(psychosis). We do not know how often these may occur.

Extremely rarely, isotretinoin may be associated with people hurting themselves (self-harm) or suicide.

If you have ever had low mood, suicidal thoughts or any other mental health issues, please talk with your dermatology team about this before starting treatment.

If you or your friends and family notice any changes in your feelings or behaviour whilst taking isotretinoin, stop taking it and contact your dermatology team to discuss whether isotretinoin is suitable for you.

If you have thoughts of harming yourself or if there are serious concerns about your mental health, you should stop taking isotretinoin and immediately seek medical help.

For further information, please also see the Royal College of Psychiatrists' information leaflet on [isotretinoin and mental health](https://bit.ly/3F5VOc1) (<https://bit.ly/3F5VOc1>).

## ISOTRETINOIN AND SEXUAL FUNCTION SIDE EFFECTS

There are rare reports of people having sexual function problems with isotretinoin. We do not know how often these may occur.

We know that sexual function problems can be related to mental health issues or other medication (such as anti-depressants), which may be taken at the same time as isotretinoin.

There are some individual reports of patients experiencing a lack of interest in sex (low libido), vaginal dryness, difficulty getting/keeping an erection, reduced sensation in the genitals.

Rarely, men have reported breast tissue development (gynaecomastia).

Some people have reported that the problems have continued after stopping treatment.

If you have any sexual function problems, discuss this with your dermatology healthcare professional before taking isotretinoin.

## INFORMATION ONLY FOR PEOPLE OF CHILD-BEARING POTENTIAL (PEOPLE WHO MAY BE ABLE TO GET PREGNANT)

You are considered to have child-bearing potential if you have a uterus and at least one ovary, unless:

- You have undergone surgical sterilisation (tubal ligation), confirmed by a healthcare professional.
- You are post-menopausal, confirmed by a healthcare professional.

### *Why must I not get pregnant on isotretinoin?*

Isotretinoin may cause **serious harm** to the development of a baby. It also increases the risk of miscarriage. You should avoid pregnancy during isotretinoin treatment and for 1 month after stopping.

### *Will isotretinoin affect future pregnancies?*

There is no evidence that suggests isotretinoin affects fertility. One month after stopping isotretinoin you may get pregnant with no additional risk to the unborn baby.

### *What is the Pregnancy Prevention Programme?*

The Pregnancy Prevention Programme is a set of rules which doctors, nurses and pharmacists must follow to protect unborn babies against the risks of exposure to isotretinoin:

- If you are a person who may be able to get pregnant, you will need to be enrolled in the Pregnancy Prevention Programme (PPP).
- Being on the PPP means you will be asked about contraception (birth control) and monitored for possibility of pregnancy. This will be before starting treatment, during treatment and 1 month after stopping.
- You will need to discuss contraception before you start isotretinoin. This may be with the GP or nurse within your own surgery or with your local sexual health/contraception clinic before you are seen by the dermatology team.
- Your dermatology healthcare professional will need to be certain you



are not pregnant when you start treatment. You must have used suitable contraception or not had sex with someone who could make you pregnant for 4 weeks before starting isotretinoin. You will need to have a negative pregnancy test. If you are having periods, you should ideally start isotretinoin on day 2 or 3 of your period.

### *What is suitable contraception?*

The Pregnancy Prevention Programme recommends **either**:

- A '**highly effective**' form of contraception (failure rates less than 1%). This may be the coil (IUD), intra-uterine system (IUS), or contraceptive implant which has been in place for at least 4 weeks.

or

- Two forms of contraception together. These may be the hormonal contraceptive pill or contraceptive injection **plus** a barrier method (such as a condom, femidom, vaginal cap).

Please discuss with your healthcare professional if you are unsure about your contraception.

Further guidance on pregnancy testing and contraception for pregnancy prevention during treatment with medicines is available here: [www.bit.ly/3RJsIH1](http://www.bit.ly/3RJsIH1).

### *What can interfere with contraception?*

Hormonal pills and implants may not work in some situations such as:

- If you are starting new medications, including antibiotics or herbal preparations, such as St John's Wort.
- If you have diarrhoea or vomiting.
- If you do not take your contraceptive pill every day.

You should check with your GP, pharmacist or family planning clinic when taking any new medications to make sure they will not affect how well the contraception works.

### *Who does not need contraception?*

You do not need contraception if there is expected to be no chance of you getting

pregnant during isotretinoin treatment and for 1 month afterwards.

This must be for one of the following reasons:

- Being medically unable to get pregnant (no child-bearing potential - see above).
- Long-term sexual abstinence (not having sex and not planning to have sex) for the duration of isotretinoin treatment and for 1 month after stopping isotretinoin treatment.
- Only having sex/sexual intercourse with a person who has no potential to make you pregnant. Examples include sex with a:
  - same-sex partner
  - person who has had a vasectomy with two confirmed tests of being sperm-free
  - transgender man.

Your need for contraception must be discussed with your dermatology healthcare professional before starting isotretinoin and **reviewed at each clinic visit**.

### *How often do I need to have pregnancy tests?*

- Pregnancy tests are usually done every month during treatment. Prescriptions are only for 30 days and must be collected and dispensed within 7 days.
- If you are using a 'highly effective' method of contraception your pregnancy tests may be less frequent and your prescription may be for longer. You may still choose to do monthly pregnancy tests at home because no contraception is 100% effective.
- If there is expected to be **no chance** of you getting pregnant (see '*Who does not need contraception?*' section above), you do not need pregnancy tests unless your situation changes.

### *What if I have unprotected sex or think I am pregnant during treatment?*

If you have unprotected sex whilst taking isotretinoin (or 1 month afterwards), you will need emergency contraception. Emergency contraception may be the 'morning-after pill' or having an emergency IUD fitted. Urgently



discuss with your doctor, pharmacy or a sexual health clinic. Stop taking oral isotretinoin.

If you miss a period, think you may be pregnant or find you are pregnant you should:

- Stop taking isotretinoin immediately.
- Seek medical advice as soon as possible.
- Inform your dermatology team.

### ***As a female-to-male transgender person, do I need to follow the same instructions?***

Female-to-male transgender people who have not had a hysterectomy can still get pregnant if they have sex with a person who can produce sperm. For this reason, female-to-male transgender individuals of child-bearing potential should be entered into the Pregnancy Prevention Programme.

### **WHERE CAN I FIND OUT MORE ABOUT ISOTRETINOIN?**

This patient guide does not provide information on all the benefits and side effects which have been associated with isotretinoin. If you would like further information, or if you have any concerns about your treatment, you should discuss this with your GP, dermatology healthcare professional or pharmacist. You should also read the patient information leaflet that comes with your medicine package (please see below).

#### ***Web links to relevant information:***

Medicines for Children 'Oral isotretinoin guide for young people' <https://bit.ly/isog4yp>

Royal College of Psychiatrists' information leaflet on isotretinoin and mental health <https://bit.ly/3F5VOc1>

British Association of Dermatologists position statement on isotretinoin and soya allergy [www.bad.org.uk/pils/isotretinoin-and-soya-allergy](http://www.bad.org.uk/pils/isotretinoin-and-soya-allergy)

#### ***Acne information***

[www.bad.org.uk/pils/acne](http://www.bad.org.uk/pils/acne)

[www.acnesupport.org.uk](http://www.acnesupport.org.uk)

[www.skinhealthinfo.org.uk/support-resources](http://www.skinhealthinfo.org.uk/support-resources)

#### ***Further resources***

Guidance on pregnancy prevention and contraception for teratogenic drugs <https://bit.ly/3RJsIH1>

Isotretinoin expert safety report – a plain-language summary of the recommendations <https://bit.ly/48JZayQ>

Roaccutane Soft Capsules - Patient Information Leaflets (PILs)

<https://bit.ly/iso10mg>

<https://bit.ly/iso20mg>

*Please note that the British Association of Dermatologists (BAD) provides web links to additional resources to help people access a range of information about their treatment or skin condition. The views expressed in these external resources may not be shared by the BAD or its members. The BAD has no control of and does not endorse the content of external links.*

**This patient guide 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 patient guide has been assessed for readability by patient representatives.***

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