▼ Isotretinoin Acknowledgement of Risk Form

Patient Details

Name of patient:	Date of birth:
NHS/CHI number:	Hospital number:
GP name and address:	

Information for PATIENTS

All medicines have benefits and risks. Isotretinoin works well to treat severe acne, but it can cause side effects. For example, your acne might get worse before it gets better; your lips can get quite dry; you can get sunburnt more easily, even if you do not normally burn. Some side effects may continue even after stopping isotretinoin. We do not know how often this happens, or for how long those side effects can last.

Isotretinoin can seriously harm an unborn baby. This is why patients **must not** become pregnant during treatment with isotretinoin and for 1 month after isotretinoin is stopped. Patients of childbearing potential (anyone who may be able to get pregnant) must enter the Pregnancy Prevention Programme.

This **Isotretinoin Acknowledgement of Risk Form** is to make sure you know about the side effects and possible risks which have been associated with isotretinoin. If you are under 18 years old, then this form is also to record that a second approved[1] named healthcare professional (HCP) has agreed that isotretinoin is a suitable medicine for you to take.

Your prescriber will go through this form with you. Please read each part of it carefully. You need to agree to all applicable points to receive isotretinoin. You will receive a copy of your completed form before starting isotretinoin treatment - please keep the copy safe.

Information for the Lead Prescriber (the prescriber initiating isotretinoin treatment)

The Lead Prescriber must complete this form for **all patients** treated with isotretinoin. The Lead Prescriber and patient (and usually a parent or guardian if under 18 years old) should go through the form together. Be aware of safeguarding concerns when talking to under 18s. The patient must be given a copy of the completed form. This form is divided into 3 sections:

1. **Isotretinoin risks:** a checklist of the risks of isotretinoin, including possible risks to mental health and sexual function.
2. **Pregnancy Prevention Programme:** all patients of childbearing potential must enter the Pregnancy Prevention Programme in order to be fully informed of the risks to an unborn baby and to prevent harm to an unborn baby from exposure to isotretinoin.
3. **Acknowledgement of risk** and agreement of a second approved named healthcare professional[1] (if applicable):
   - **All patients** (and usually a parent or guardian if under 18 years old) must sign to confirm they are aware of the risks of isotretinoin.
   - The Lead Prescriber must sign to confirm they have explained the risks to the patient.
   - In patients under 18 years old, the Lead Prescriber must also document the agreement of the second approved named healthcare professional that isotretinoin is the most appropriate treatment option.

WARNING: Use of isotretinoin for indications not listed in the Summary of Product Characteristics is outside the licence. Prescribers are reminded of the General Medical Council's guidance in good practice in prescribing and managing medicines and devices[2] and also Decision Making and Consent[3]

1. https://www.gov.uk/guidance/isotretinoin-an-expert-review-of-suspected-psychiatric-and-sexual-side-effects
2. https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices
3. https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/decision-making-and-consent

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1. Isotretinoin risks

The Lead Prescriber and patient must go through every point in this checklist and tick once completed. All patients must complete this section.

	Prescriber explained	Patient acknowledges
I have discussed my treatment options for acne with my prescriber.	✔	☐
I have read the relevant patient information on isotretinoin (British Association of Dermatologists 'Isotretinoin Patient Guide' and/or Medicines for Children 'Oral isotretinoin Guide for young people'.)[4] I understand there are a range of possible side effects associated with taking isotretinoin. I understand that some side effects may continue after treatment. I agree to read the patient information leaflet that comes with the medicine before starting isotretinoin.	✔	☐
I understand that isotretinoin may be linked with possible mental health and sexual function side effects. Possible mental health side effects include low mood, depression, anxiety, agitation, aggression, self-harm, suicidal thoughts/attempts, psychosis (loss of touch with reality).	✔	☐
I have completed a mental health assessment before treatment[5]. I have been directed towards appropriate mental health support if there are concerns.	✔	☐
I have had blood tests for my liver and blood fat levels before treatment.	✔	☐
I agree to attend regular clinic appointments during my treatment for monitoring.	✔	☐
I understand I **must not** donate blood during treatment with isotretinoin and for 1 month afterwards.	✔	☐
I will not share my isotretinoin capsules with anyone else.	✔	☐
I will inform my family and/or friends that I am taking isotretinoin. I will tell them about possible side effects to look out for. I will ask them to tell me to contact my prescriber or someone in their team if needed.	✔	☐
If I have thoughts of harming myself or if there are serious concerns about my mental health I will stop taking isotretinoin and immediately seek medical help (see end of document for contact details).	✔	☐
I have been given information on how to get in contact with my prescriber or someone in their team. I will contact them if I have concerns about the side effects of isotretinoin or if I stop treatment (see section 3.3 of this form).	✔	☐

Please continue to section 2: Pregnancy Prevention Programme

4. Please note, these materials are not produced or maintained by the marketing authorisation holder.
5. Baseline mental health assessment should include details of mental health history (including previous self-harm and contact with mental health services), discussion about current mental wellbeing (including impact of acne) and completion of validated mental health Patient Reported Outcome Measures – e.g. PHQ-9/PHQ-A and GAD-2 as a minimum.

2. Pregnancy Prevention Programme

Does the patient have childbearing potential?

A person has childbearing potential if they have a uterus and at least one ovary unless they:

a Have undergone surgical sterilisation (tubal ligation), confirmed by a healthcare professional.

b Are post-menopausal, confirmed by a healthcare professional.

If 'No' go to section 3: Acknowledgment of risk

All patients with childbearing potential (anyone who may be able to get pregnant) must be entered into the Pregnancy Prevention Programme.

	Prescriber explained	Patient acknowledges
I understand that isotretinoin can seriously harm an unborn baby and increases the risk of miscarriage when taken during pregnancy. I know that I must not get pregnant whilst taking isotretinoin and for 1 month after stopping treatment.	☑	☐
Use of contraception - complete i) OR ii) as applies		
i) I have been using contraception for the last 4 weeks. I agree to pregnancy testing during treatment. I understand and agree to use the following contraception during treatment and for 1 month afterwards (either a or b): a. A hormonal contraceptive pill or contraceptive injection **plus** a barrier method (i.e. a condom, female condom, vaginal cap). b. The coil (IUD), intra-uterine system (IUS), or contraceptive implant (highly effective user-independent forms of contraception) which have been in place for at least 4 weeks.	☑ ☑	☐ ☐
ii) The prescriber and I agree I do not need to use contraception because there is expected to be **no risk of pregnancy**[6] during treatment and for 1 month after treatment. If my situation changes, I will let my prescriber know and take/use appropriate contraception to avoid pregnancy. **Prescriber to document here the agreed reason that no contraception is needed. Go to 'Unprotected Sex or Pregnancy' section.** . .	☑	☐
I am aware that any contraception can fail. I know there is a very small chance of getting pregnant even if I am on contraception.	☑	☐
Hormonal contraception can be less effective in some situations. I understand I may need to use extra contraception if: • I am starting new medications, including antibiotics or herbal preparations such as St John's Wort • I have diarrhoea and vomiting • I have missed taking my contraception	☑	☐
I understand the first prescription for isotretinoin can only be given after I have had one negative pregnancy test checked by the prescriber.	☑	☐
I understand I need a pregnancy test 1 month after stopping treatment because the risks to an unborn baby last for 1 month after the last dose.	☑	☐
The contraceptive methods and pregnancy test results have been recorded in my medical records.	☑	☐

Continued overleaf.

6. Reasons for not requiring contraception (expectation of no risk of pregnancy) include any one of the following:
   - Medically unable to become pregnant (no uterus/ hysterectomy/ oophorectomy, sterilisation or postmenopausal as previously outlined).
   - Only having sex/sexual intercourse with a person who has no potential to make them pregnant.This must be for the duration of isotretinoin treatment and for 1 month after stopping isotretinoin treatment. Examples include sex with a:
     - Person of the same-sex
     - Person who has had a vasectomy with two confirmed tests of being sperm-free
     - Transgender man
   - Long-term sexual abstinence (no sexual activity) for the duration of isotretinoin treatment and for 1 month after stopping isotretinoin treatment. This should be confirmed at each clinic visit.

Unprotected Sex or Pregnancy		
I understand I will need to seek medical advice **as soon as possible** if I have unprotected sex with someone who can make me pregnant. I will take emergency contraception (morning-after pill or have an emergency IUD fitted).	✔	☐
I will stop my isotretinoin immediately, inform my dermatology team and seek medical advice if I miss my period, become pregnant, or suspect that I have become pregnant. This applies during isotretinoin treatment and for 1 month after stopping.	✔	☐
If I get pregnant despite the above advice, I understand I will need to seek medical advice as soon as possible.	✔	☐

Please continue to section 3: Acknowledgment of risk

3. Acknowledgment of risk

3.1 Patients

All patients

The patient (and if applicable their parent or guardian[7]) must sign to confirm that they understand the possible risks of isotretinoin.

I confirm I understand the possible risks of isotretinoin.	Yes ☐ No ☐

Name of patient:	Signature of patient:	Date of signature:
Name of parent or guardian (if applicable[7]):	Signature of parent or guardian (if applicable):	Date of signature:

Patients with childbearing potential (tick A, B or C as appropriate).

☐ **A - I confirm** I do not require contraception because there is no risk of pregnancy during treatment and for 1 month after treatment. I do not require pregnancy testing. I will let my prescriber know if my situation changes.

☐ **B - I confirm** I have been using the contraceptive implant or have had a coil (IUD) or intra-uterine system (IUS) for at least 4 weeks. I agree to pregnancy testing at follow-up appointments. I may choose to do monthly pregnancy tests at home because no contraception is 100% effective. I will let my prescriber know if my situation changes.

☐ **C - I confirm** I have been using a hormonal contraceptive pill or contraceptive injection **plus** I agree to use a barrier method (i.e. a condom, female condom, vaginal cap). I agree to pregnancy testing every 30 days during treatment. My prescriptions will be for 30 days. Prescriptions will need to be collected within 7 days.

Signature of patient:	Date of signature:

3.2 Lead Prescriber

I confirm that the possible risks of isotretinoin have been explained to the patient.

Pregnancy Prevention Programme status: (tick 'Not applicable', A, B or C, as appropriate). For patients in groups 'Not applicable', A and B, once stable on isotretinoin (after the first 1-3 months) the prescription may be for longer than 30 days (up to 12 weeks).

Not applicable (no childbearing potential)	Group A	Group B	Group C
☐	☐	☐	☐

Name of Lead Prescriber: Magnus Lynch	Role and unique identifier: Consultant Dermatologist, GMC 6064789
Signature of Lead Prescriber: M Lynch	Date of signature:

7. A parent or guardian should be asked to sign if under 18 years old, unless, in the opinion of the prescriber, this is not in the best interests of the patient. This reason should be documented in the patient record.

3.3 Agreement of second approved named healthcare professional for patients under 18 years old (to be completed by lead prescriber prior to initiation of treatment):

A second approved healthcare professional or multi-disciplinary team agrees that treatment with isotretinoin is appropriate (i.e. the patient has severe acne for which other standard treatments have been sufficiently tried and were ineffective).

Name of second approved healthcare professional:

Role and place of work:

Date agreed:

If MDT decision, name of lead MDT clinician and date of meeting:

Once completed, a copy of this form should be given to the patient or their parent(s) or guardian(s) and this form should be stored in their medical notes and shared with all healthcare professionals if needed.

Contact details of dermatology team for all patients
Dr Magnus Lynch
Email: contact@drmagnuslynch.com
Telephone: 0203 389 6076

See below for advice on mental health contacts.

Remember:
Talk to your dermatology team or GP about your treatment or if you have any concerns. You should stop taking isotretinoin and contact your dermatology team for further advice if you have serious concerns about your mental health or thoughts of harming yourself or other serious side effects.

If you are in mental health crisis or feel suicidal during treatment, contact your local mental health crisis team, or NHS on 111 for support. Alternatively, you can call the Samaritans to talk about anything that is upsetting you, 24 hours a day, 365 days a year. You can call 116 123 (free from any phone).

If you have seriously harmed yourself or feel that you may be about to harm yourself, call 999 for an ambulance or go straight to A&E.

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects that you may experience.

Pregnancies occurring during treatment and within 1 month following discontinuation of treatment should be reported to the MHRA and the company named in the patient information leaflet who will follow up with you to record the pregnancy outcome.

Report any suspected adverse reactions. Adverse events should be reported to the MHRA, and the company listed in the patient's package information leaflet. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.