FOR HEALTHCARE PROFESSIONAL USE ONLY

Prescriber Checklist
Acknowledgement Form for Prescribing Isotretinoin to Female Patients

The potential for pregnancy must be assessed for all female patients prescribed Isotretinoin.

A woman has a potential for pregnancy if one of the following applies:

Is a sexually mature woman who:

1. has not had a hysterectomy or bilateral oophorectomy
2. is not in a natural postmenopause for a minimum of 24 consecutive months (i.e., menstruated at a certain point in the last 24 consecutive months).

Before initiating Isotretinoin therapy in a female patent, the following checklist must be completed by the Prescriber and kept with the patient notes to document compliance with the Isotretinoin Pregnancy Prevention Programme. After completion, a copy of this document should be given to the patient.

Isotretinoin belongs to the retinoid class of drugs that cause severe birth defects. Foetal exposure to Isotretinoin, even for short periods, presents a high risk of congenital malformations. Isotretinoin is therefore strictly contraindicated in women of child-bearing potential, unless all conditions in the Isotretinoin Pregnancy Prevention Programme are fulfilled.

As the prescriber, you must make sure that the risk of serious harm from drug exposed pregnancy is fully understood by all female patients before treating them with Isotretinoin.

This checklist should also be used in all follow-up visits with women of childbearing potential. Please use the patient reminder card to support your discussion with the patient.

▼This medicinal product is subject to additional monitoring.

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

Healthcare professionals are asked to report any suspected adverse reactions. Adverse events should be reported to the Malta Medicines Authority and the company listed in the patient's package information leaflet.

Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at http://www.medicinesauthority.gov.mt/adrportal, and sent by post or email to the Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 : postlicensing.medicinesauthority@gov.mt

Alternatively you may report suspected adverse drug reactions to the Marketing Authorisation Holder at Ennogen Healthcare Ltd, Unit G4, Riverside Industrial estate, Riverside Way, Dartford, DA1 5BS, UK. Email address: info@ennogen.com

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Is the patient a woman of childbearing potential? YES ☐ NO ☐ If 'No' go to section 4

Women of childbearing potential

Review the below statements, explain them to the patient and record confirmation of this and acknowledgment from the patient in this form. If the answer to any of these questions is NO, Isotretinoin must not be prescribed.

	Prescriber confirm: I have explained this to my patient	Patient confirm: I have understood this
Is the patient suffering from a severe form of acne, which is resistant to standard therapies?	yes ☐ no ☐	yes ☐ no ☐
1. Teratogenicity		
The patient understands that Isotretinoin belongs to a class of drugs (retinoids) known to cause severe birth defects and that they must not get pregnant whilst taking it. Isotretinoin also increases the risk of miscarriage when taken during pregnancy.	yes ☐ no ☐	yes ☐ no ☐
2. Contraception		
The patient understands that she must consistently and correctly use at least 1 highly effective method of contraception (i.e. a user-independent form such as an intra-uterine device or implant) or 2 complementary methods of birth control (i.e. user-dependent forms such as oral contraceptive and barrier method) before and during treatment.	yes ☐ no ☐	yes ☐ no ☐
The patient understands that the risk persists even after the medication is stopped and that she must not get pregnant within 1 month after stopping treatment.	yes ☐ no ☐	yes ☐ no ☐
The patient has received advice on contraception which is appropriate for her and has committed to using it throughout the risk period.	yes ☐ no ☐	yes ☐ no ☐
The patient is aware of the risk of contraceptive failure.	yes ☐ no ☐	yes ☐ no ☐
3. Pregnancy Testing & Monthly Prescriptions		
The first prescription for Isotretinoin can only be given after the patient has had one negative medically supervised pregnancy test. This is to make sure she is not already pregnant before starting treatment.	yes ☐ no ☐	yes ☐ no ☐
Patient understands that in order to support regular follow up, including pregnancy testing and monitoring, ideally the prescription should be limited to 30 days.	yes ☐ no ☐	yes ☐ no ☐
Patient understands the need for and agrees to pregnancy testing before, during and after treatment.	yes ☐ no ☐	yes ☐ no ☐
Patient understands the need to do a pregnancy test 1 month after stopping treatment because the drug stays in the body for 1 month after the last dose and can damage an unborn baby if pregnancy occurs.	yes ☐ no ☐	yes ☐ no ☐
The contraceptive methods and pregnancy test results were recorded in the patient's medical records.	yes ☐ no ☐	yes ☐ no ☐
The patient knows to contact their doctor if they have unprotected sex, miss their period, become pregnant, or suspect that they have become pregnant during the risk period.	yes ☐ no ☐	yes ☐ no ☐
If pregnancy occurs, treatment must be stopped and the patient should be referred to an expert physician specialised or experienced in teratology for advice.	yes ☐ no ☐	yes ☐ no ☐
The patient has received a reminder card and copy of this form.	yes ☐ no ☐	yes ☐ no ☐
4. Other Precautions		
Patient understands that Isotretinoin has been prescribed to her only and must not be shared with others.	yes ☐ no ☐	yes ☐ no ☐
Patient understands that she must not donate blood during treatment with Isotretinoin and for one month after discontinuation due to the potential risk to the foetus of a pregnant transfusion recipient.	yes ☐ no ☐	yes ☐ no ☐

Prescriber Signature..... Patient (or guardian if under 18) signature ..... Date .....

To order further copies of the Oral Isotretinoin PPP materials
please email: oralisotretinoinppp@linney.com
or call: 0370 7030602

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