FOR USE IN IRELAND

Physician Checklist/Acknowledgement Form for Prescribing Roaccutane® (isotretinoin) to Female Patients

This material is provided by CHEPLAPHARM Registration GmbH as a licence requirement for this medicine and forms part of the Roaccutane® Risk Management Plan

The potential for pregnancy must be assessed for all girls and women of childbearing potential treated with Roaccutane®

Is the patient a girl or woman of childbearing potential? ☐ Yes ☐ No

A woman of childbearing potential is defined as a pre-menopausal female who is capable of becoming pregnant.

This form is to be completed by the physician and patient at initial and follow-up visits for all female patients prescribed Roaccutane®. The signed document should be kept with the patient notes to document compliance with the Roaccutane® Pregnancy Prevention Programme. After completion, a copy of this document should be given to the patient.

Roaccutane® belongs to the retinoid class of drugs that cause severe birth defects. Foetal exposure to Roaccutane®, even for short periods, presents a great risk of very severe and serious congenital malformations. Roaccutane® is therefore strictly contraindicated during pregnancy and in women of childbearing potential unless all the conditions of the Roaccutane® Pregnancy Prevention Programme are fulfilled.

As the prescribing doctor, you must ensure that the teratogenic risk and necessary precautions are fully understood and acknowledged by all female patients before treating them with Roaccutane®.

Please use the patient reminder card to support your discussion with the patient.

Review the below statements, discuss them with your patient and ensure that she understands and acknowledges the risks and necessary precautions related to the use of Roaccutane®. Record confirmation of this on the form. If the answer to any of these questions is NO, Roaccutane® must not be prescribed.

PART A: To be completed by the physician

I confirm that the patient is prescribed Roaccutane® because she is suffering from a severe form of acne (such as nodular or conglobate acne or acne at risk of permanent scarring) resistant to adequate courses of standard therapy with systemic anti-bacterials and topical therapy.	☐ Yes	☐ No

I confirm that I have discussed the following information with my patient:

Teratogenicity

Roaccutane® belongs to a class of drugs (retinoids) known to cause severe and serious foetal malformations, including central nervous system abnormalities, facial dysmorphia, cleft palate, external ear abnormalities, eye abnormalities, cardiovascular abnormalities, thymus gland abnormality and parathyroid gland abnormalities.	☐ Yes	☐ No
Roaccutane® increases the risk of spontaneous abortion when taken during pregnancy.	☐ Yes	☐ No
Roaccutane® must not be used in pregnancy.	☐ Yes	☐ No

Contraception

The need for consistent and correct use, without interruption, of 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 user-dependent methods of contraception (e.g. oral contraceptive and barrier method).	☐ Yes	☐ No
The need for contraception, as described above, for at least 1 month before treatment, throughout the entire duration of treatment and for at least 1 month after stopping treatment as the risk persists until the product is completely eliminated, which is within 1 month following the end of treatment.	☐ Yes	☐ No
I have provided advice on contraception which is appropriate for the patient, or I have referred her for contraception services as appropriate.	☐ Yes	☐ No

Pregnancy Testing & Monthly Prescriptions

The need for a medically supervised pregnancy test at least 1 month after the patient has started using contraception and shortly (preferably a few days) prior to the first prescription for Roaccutane® to ensure that the patient is not pregnant when she starts treatment.	☐ Yes	☐ No
The need for prescriptions to ideally be limited to 30 days, in order to support regular follow up, including pregnancy testing and monitoring.	☐ Yes	☐ No
The need for pregnancy testing during (ideally monthly) and 1 month after stopping treatment, as the risk of severe and serious foetal malformations persists until the product is completely eliminated.	☐ Yes	☐ No
The need to contact her doctor immediately in case of suspected or inadvertent pregnancy during treatment or within 1 month after stopping treatment.	☐ Yes	☐ No
The need to stop treatment immediately in case of suspected or inadvertent pregnancy and need for patient referral to an expert physician specialised or experienced in teratology for advice (in case of pregnancy).	☐ Yes	☐ No
I have provided the patient with a copy of the patient reminder card.	☐ Yes	☐ No

Other Precautions

Roaccutane® must not be shared with others.	☐ Yes	☐ No
The patient must not donate blood during treatment with Roaccutane® and for 1 month after discontinuation due to the potential risk to the foetus of a pregnant transfusion recipient.	☐ Yes	☐ No

Doctor Name: Doctor Signature: Date:

Pregnancies occurring during treatment and within 1 month following discontinuation of treatment should be reported to Red Line Pharmacovigilance Ltd, Challenge House, Sherwood Drive, Bletchley, Milton Keynes, MK3 6DP, United Kingdom; Tel: +353 1800 123 000; Email: cheplapharm@redlinepv.co.uk; who will follow up with you to record the pregnancy outcome.

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PART B: To be completed by the patient

The doctor has explained the following information to me and I confirm that I have understood this:

Why I have been prescribed Roaccutane®.	☐ Yes	☐ No

Teratogenicity

That Roaccutane® belongs to a group of medicines called retinoids (for treatment of acne) and can seriously harm an unborn baby (the medicine is said to be 'teratogenic'). It can cause serious abnormalities of the unborn baby's brain, face, ear, eye, heart and certain glands (thymus gland and parathyroid gland).	☐ Yes	☐ No
That Roaccutane® also makes a miscarriage more likely even if only taken for a short time during pregnancy.	☐ Yes	☐ No
That I must not get pregnant whilst taking Roaccutane®, or for 1 month after stopping this treatment as some medicine may still be left in my body.	☐ Yes	☐ No
That I must not take Roaccutane® if I am pregnant or think I might be pregnant.	☐ Yes	☐ No

Contraception

That I must use at least 1 very reliable method of contraception (for example an intra uterine device or contraceptive implant) or 2 effective methods that work in different ways (for example a hormonal contraceptive pill and a condom).	☐ Yes	☐ No
That I must use contraception as described above for 1 month before taking Roaccutane®, during treatment and for 1 month after stopping treatment, as some medicine may still be left in my body after stopping treatment.	☐ Yes	☐ No
We discussed the possibilities of effective contraception, or we planned a consultation with a professional experienced in advising on effective contraception.	☐ Yes	☐ No

Pregnancy Testing & Monthly Prescriptions

That my doctor will ask me to take a pregnancy test, before I start treatment. The test must show that I am not pregnant when starting treatment with Roaccutane®.	☐ Yes	☐ No
That the prescription is limited to 30 days in order to support regular follow up, including pregnancy testing and monitoring.	☐ Yes	☐ No
The need for pregnancy testing during (ideally monthly) and 1 month after stopping treatment, because some medicine may still be left in my body and could damage an unborn baby if pregnancy occurs.	☐ Yes	☐ No
The need to contact my doctor immediately if I have unprotected sex, miss a period, am pregnant, or think that I might be pregnant while taking Roaccutane® or within 1 month after stopping treatment.	☐ Yes	☐ No
The need to stop taking Roaccutane® straight away if I become pregnant or think I might be pregnant. That my doctor may send me to a specialist for advice.	☐ Yes	☐ No
I have received a copy of the patient reminder card.	☐ Yes	☐ No

Other Precautions

That I must not share this medicine with others.	☐ Yes	☐ No
That I must not donate blood during treatment with Roaccutane® and for 1 month after stopping treatment because an unborn baby could be harmed if a pregnant patient receives my blood.	☐ Yes	☐ No

Patient Name:	Patient Signature:	Date:
Parent/Legal Guardian (if patient is under the age of 16):	Parent/Legal Guardian Signature:	Date:

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Reporting of suspected adverse events or reactions

Reporting suspected adverse events or reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse events or reactions (see details below).

In the event of a suspected adverse event, please report it to:
Red Line Pharmacovigilance Ltd
Challenge House, Sherwood Drive, Bletchley, Milton Keynes, MK3 6DP, United Kingdom
Email: cheplapharm@redlinepv.co.uk
Telephone: +353 1800 123 000

Alternatively, suspected adverse reactions should be reported to:
HPRA Pharmacovigilance
The Health Products Regulatory Authority
Website: www.hpra.ie

Further Information

For electronic copies of this risk minimisation material, refer to www.hpra.ie and download the required material (enter 'Roaccutane' or 'isotretinoin' in the search box and click on 'EdM' next to any of the medicines that appear). Alternatively if you would like hard copies, please contact cheplapharm@redlinepv.co.uk

For further information about Roaccutane®, please contact Red Line Pharmacovigilance Ltd, Challenge House, Sherwood Drive, Bletchley, Milton Keynes, MK3 6DP, United Kingdom.
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