



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

Roaccutane®
Isotretinoin

Roaccutane® – Physician Checklist /Acknowledgement Form for Prescribing to Female Patients

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, Roaccutane must not be prescribed.

	I have explained this to my patient.		Patient confirm: I have understood this.	
Is the patient suffering from a severe form of acne, severe form of psoriasis or severe disorder of keratinisation which is resistant to standard therapies?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	yes	no	yes	no
Teratogenicity				
The patient understands that Roaccutane® belongs to a class of drugs (retinoids) known to cause severe birth defects and that they must not get pregnant whilst taking it. Roaccutane® also increases the risk of miscarriage when taken during pregnancy.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	yes	no	yes	no
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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	yes	no	yes	no
The patient is aware of the risk of contraceptive failure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	yes	no	yes	no

Doctor confirm:
I have explained this
to my patient.

Patient confirm:
I have understood
this.

Pregnancy Testing & Monthly Prescriptions

The first prescription for Roaccutane® 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 appointment table (included in patient reminder card).

yes no yes no

The patient has received a copy of the educational package.

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

Doctor confirm:
I have explained this
to my patient.

Patient confirm:
I have understood
this.

Other Precautions

Patient understands that Roaccutane® 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 Roaccutane® and for one month after discontinuation due to the potential risk to the foetus of a pregnant transfusion recipient.

yes no yes no

Signature Signature Signature

Date Date

Pregnancies occurring during treatment and within 1 month following discontinuation of treatment should be reported to the MAH at [local operating company to insert pharmacovigilance contact information], who will follow up with you to record the pregnancy outcome.

Signature of parent or legal guardian is necessary if the patient is under the age of <[age]>.

*The potential for pregnancy must be assessed
for all female patients prescribed Roaccutane®*

Is the patient a woman of childbearing potential?

yes no

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).

This checklist is to be completed by the Physician for all female patients prescribed Roaccutane® and kept with 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. Fetal exposure to Roaccutane®, even for short periods, presents a high risk of congenital malformations. Roaccutane® is therefore strictly contraindicated in women of childbearing potential, unless all conditions in the Roaccutane® Pregnancy Prevention Programme are fulfilled.

As the prescribing doctor, 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 Roaccutane®.

Before initiating Roaccutane® therapy in a female patient, the following checklist must be completed and stored in the patient's notes. 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.

Published by

Roche Servicios
S.A.
Medical Affairs
Centro América
y el Caribe

Version 3
© 2018

All trademarks mentioned
enjoy legal protection.

Material created by Roche

All rights reserved - total or partial reproduction is prohibited without prior written
authorization from Roche Servicios S.A.