

Roaccutane[®] (isotretinoin) Acknowledgement Form for Female Patients

To be completed and signed by the patient or parent/guardian

By signing this acknowledgement form, you declare that you have read and understood each of the items listed below, and that you accept the risks and necessary precautionary measures associated with Roaccutane treatment. Please read each item below carefully, and sign this acknowledgement form only if you fully understand each item and agree to follow your doctor's instructions. If a parent or guardian is required to sign the acknowledgement form, he or she must also read and understand each item before signing the agreement.

Do not sign this agreement, and do not take Roaccutane if there is anything that you do not understand about the information you have received about using Roaccutane.

- I understand that there is a very high risk that my unborn baby could have severe birth defects if I am pregnant or become pregnant while taking Roaccutane. This is why I must not be pregnant while taking Roaccutane.
- I understand that I must not take Roaccutane if I am pregnant.
- I understand that I must not get pregnant during the entire time of my treatment, and for one month after the end of my treatment with Roaccutane.
- I understand that I must use at least 1, and preferably 2 separate, effective forms of contraception at least one month before starting treatment, throughout the treatment period, and for at least one month after stopping the treatment. The only exception is if my doctor considers that there is no risk of pregnancy.
- I understand that I cannot get a prescription for Roaccutane unless I have a negative pregnancy test result carried out under medical supervision during the first 3 days of my period immediately prior to starting Roaccutane therapy. I accept the need for monthly follow up visits and more pregnancy tests as decided by my doctor. I will also have a pregnancy test 5 weeks after stopping Roaccutane therapy.
- I understand that I should not start taking Roaccutane until I am sure that I am not pregnant and have a negative pregnancy test.
- I have read and understand the following materials my prescriber has given to me: Roaccutane – the facts you need and Contraception advice for people taking Roaccutane.
- I understand that I must stop taking Roaccutane immediately and inform my doctor if I get pregnant, miss my period, stop using contraception methods, or have sex without using contraception. I understand that if I become pregnant my doctor may refer me to a physician specialised or experienced in birth defects for evaluation and advice.

My prescriber has answered all my questions about Roaccutane and I accept the risks and precautionary measures involved, which have been fully explained to me.

Patient signature _____

Date _____

Parent/Guardian signature (if required) _____

Date _____

Patient name (print) _____