# ROACCUTANE (ISOTRETINOIN) PREGNANCY PREVENTION PROGRAMME
# ACKNOWLEDGEMENT FORM FOR FEMALE PATIENTS

**To be completed and signed by the patient (parent or guardian)**

Isotretinoin can cause severe birth defects to an unborn baby if it is taken – even in small amounts – during pregnancy and there is an **extremely high risk** that you will have a severely deformed baby:

- If you are pregnant when you start taking isotretinoin.
- If you become pregnant while you are taking isotretinoin.
- If you become pregnant within 1 month after stopping treatment with isotretinoin.

Do not sign this acknowledgement form and do not take isotretinoin if there is anything that you do not understand about the information you have received about using isotretinoin.

My treatment with isotretinoin has been personally explained to me by my doctor. The following points of information, among others, have been specifically discussed and made clear to me:

1. I understand that **severe birth defects** have occurred in babies of females who took isotretinoin during pregnancy.
2. I understand that I must not take isotretinoin if I am pregnant.
3. I understand that I must use at least 1 and preferably 2 separate, effective forms of contraception for at least one month before starting treatment, throughout the treatment period and for at least one month after stopping the treatment.
4. I am fully aware of the risks of possible contraceptive failure, as explained to me by my doctor.
5. I agree to talk to my doctor about any medicines or herbal products I plan to take during my isotretinoin treatment, because hormonal contraception methods (for example, the pill) may not work if I am taking certain medicines or herbal products such as St John's wort.
6. I understand that I should not start taking isotretinoin until I am sure that I am not pregnant and have had a negative pregnancy test if I am at risk of becoming pregnant.
7. I understand that I may require monthly pregnancy tests during my treatment with isotretinoin and that my doctor will discuss this with me during each follow up visit.
8. I understand that I will have to have a pregnancy test 5 weeks after stopping isotretinoin therapy if I am at risk of becoming pregnant.
9. I have read and understand the following materials my doctor has given to me: the ***Patient Information Brochure*** and the ***Brochure on Contraception***.
10. I understand that I must stop taking isotretinoin right away and contact my doctor or consultant or GP if I get pregnant, miss my period, stop using the contraception methods, or have sex without using contraception during my treatment with isotretinoin or in the month after I have stopped taking isotretinoin.
11. I understand, if I become pregnant my doctor may refer me to a physician specialised or experienced in birth defects for evaluation and advice.

***My doctor has answered all my questions about isotretinoin and I understand 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) _____