

Toctino® (alitretinoin) Pregnancy Prevention Programme

Acknowledgement Form for Female Patients

To be completed and signed by the patient, parent or guardian.

Toctino has a high potential to cause severe birth defects to an unborn baby if it is taken – even in small amounts or for short periods of time 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 Toctino
- If you become pregnant while you are taking Toctino
- If you become pregnant within one month after stopping treatment with Toctino

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

My treatment with Toctino 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 Toctino belongs to a class of drugs (retinoids) known to cause severe birth defects when taken during pregnancy.
2. I understand that I must not take Toctino if I am pregnant or become pregnant.
3. I understand that I must use one, preferably two 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, whether bought or prescribed, or herbal products I plan to take during my Toctino 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 Toctino until I am sure that I am not pregnant and have had a negative pregnancy test.
7. I understand that I will require monthly pregnancy tests during my treatment with Toctino 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 Toctino therapy.
9. I have read and understood the following materials which my doctor has given to me: the 'Patient Information Brochure' and the 'Information About Contraception' brochure.
10. I understand that I must stop taking Toctino right away and contact my doctor, consultant or GP if I get pregnant, miss my period, stop using the agreed contraception methods, or have sexual intercourse without using contraception during my treatment with Toctino or in the month after I have stopped taking Toctino.
11. 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 doctor has answered all my questions about Toctino and I understand the risks and precautionary measures involved, which have been fully explained to me.

Patient Signature _____

Date _____

Patient Name (print) _____