



Pregnancy Prevention Programme

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

Toctino[®] (alitretinoin)


About this brochure

This brochure contains important information about your treatment with Tactino and the risk of possible birth defects when taking this medicine. It is part of the Tactino Pregnancy Prevention Programme. Before taking Tactino, you should read this brochure carefully to understand some important facts about this medicine.

This guide complements but does not replace the instructions given to you by your doctor or pharmacist. Please read the brochure all the way through.

Further important information about Tactino including how to take it and possible side effects and special warnings are included in the patient information leaflet supplied in each pack of Tactino. Please take time to read the pack leaflet carefully and follow the instructions it contains.

If you have any questions or concerns about taking Tactino after reading this brochure or the pack leaflet, please discuss these with your doctor.




Information about birth defects

The active ingredient of Toctino is alitretinoin. Alitretinoin belongs to a class of medicines (retinoids) known to cause severe birth defects if used in pregnant women. This means that if you take Toctino during pregnancy there is a very high risk that your baby will be born with birth defects.

In addition, there is an increased risk that you could suffer a miscarriage if you take Toctino whilst you are pregnant. For these reasons women of childbearing potential are not allowed to use Toctino, unless all of the instructions given in the Pregnancy Prevention Programme are being followed.

Important information for female patients

- You must not use Toctino if you are pregnant
 - Stop taking Toctino and contact your doctor immediately, if you have unprotected sex, miss your period or become pregnant while you are taking Toctino or in the month after you have stopped treatment. Signs and symptoms of a pregnancy vary from individual to individual, but can include bleeding, breast pain, nausea and vomiting
 - You will get your first prescription only after you have had at least two negative medically supervised pregnancy tests 4 weeks apart or if your doctor can confidently exclude the possibility that you will become pregnant, for example following hysterectomy
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- If you are at risk of becoming pregnant you will have a pregnancy assessment every month during your Tactino therapy, and a final pregnancy test needs to be done 5 weeks after your Tactino treatment has finished. You can only get a prescription each month by returning to your specialist or doctor to have a pregnancy assessment. Your doctor will confirm the arrangements for performing the medically supervised pregnancy tests
- You should discuss reliable methods of contraception with your doctor or with a family planning advisor. One, preferably two methods of effective contraception, including a barrier method, will have to be used for one month before treatment, during treatment and for one month after stopping treatment. Because no method of contraception is totally reliable the use of two methods is preferred. One of the methods used should be a primary method, for example the pill or other hormonal contraceptives or intrauterine devices. Detailed information about the possible choice of effective methods can be found in the brochure 'Information About Contraception'. Your doctor will provide you with a copy of this brochure
- Even if your menstrual period is irregular or missing you will still have to continue to strictly apply your selected contraceptive methods during Tactino treatment. The same is true if you are currently sexually inactive

- Your doctor will ask you to confirm in writing that you have understood about the high risk of birth defects for your unborn child if you become pregnant whilst taking Toctino or within a month of stopping treatment. You will also have to confirm that you understand and accept the need for continuous reliable contraception before, during and for one month after stopping treatment
- Do not breast feed during Toctino treatment or for one month after you have stopped taking Toctino as Toctino can pass into breast milk and may harm the baby
- Talk to your doctor if you plan to take other medicines whether bought or prescribed or any herbal products, particularly if you are taking contraceptive pills or other hormonal contraceptives. Certain medicines and herbal supplements such as St John's Wort have been shown to make contraceptives less effective. You should therefore avoid taking St John's Wort during treatment with Toctino
- This medication has been prescribed personally for you. Do not share it with anyone else, particularly other female patients, even if they appear to have the same condition as you
- Do not donate blood during treatment or within one month after stopping treatment, since the person to whom your blood will be transfused could be pregnant and this would place their unborn baby at risk of birth defects
- Return all unused Toctino to your doctor or pharmacist at the end of treatment



Important information for male patients

- Do not donate blood during treatment with Tocrino or within one month of stopping treatment. If a pregnant woman were to receive your blood, her unborn baby would be placed at risk of severe malformations
 - Return all unused Tocrino to your doctor or pharmacist at the end of treatment
 - Do not share Tocrino with anyone else, particularly females, even if they appear to have the same condition as you
 - Studies have shown small quantities of Tocrino in semen. These levels are considered too low to harm the unborn baby of your female partner
 - Based on limited animal studies male fertility may be affected by treatment with Tocrino
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