Pregnancy Prevention Program

HCP Information Brochure

The potential for pregnancy must be assessed for all female patients prescribed Toctino

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 Toctino and kept with patient notes to document compliance with the Toctino Pregnancy Prevention Programme. After completion, a copy of this document should be given to the patient.

Toctino belongs to the retinoid class of drugs that cause severe birth defects. Fetal exposure to Toctino, even for short periods, presents a high risk of congenital malformations. Toctino is therefore strictly contraindicated in women of childbearing potential, unless all conditions in the Toctino 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 Toctino

Before initiating Toctino 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

Women of childbearing potential

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, Toctino must not be prescribed.

	Doctor confirm: I have explained this to my patient [YES/NO]
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?	
Teratogenicity	
I have explained the patient that Toctino belongs to a class of drugs (retinoids) known to cause severe birth defects and that she must not get pregnant whilst taking it. Toctino also increases the risk of miscarriage when taken during pregnancy.	
Contraception	
I have explained the patient 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.	
I have explained the patient that the risk persists even after the medication is stopped and that she must not get pregnant within 1 month after stopping treatment.	
The patient has received advice on contraception which is appropriate for her and has committed to using it throughout the risk period.	
The patient is aware of the risk of contraceptive failure.	
Pregnancy Testing & Monthly Prescriptions	
The first prescription for Toctino 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.	
I have explained the patient that in order to support regular follow up, including pregnancy testing and monitoring, ideally the prescription should be limited to 30 days.	
I have explained the patient the need for and she agrees to pregnancy testing before, during and after treatment.	

I have explained the patient 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.	
The patient has received a copy of the educational package.	
I have explained the patient to contact her doctor if she has unprotected sex, misses her period, becomes pregnant, or suspects that she has become pregnant during the risk period.	
If pregnancy occurs, treatment must be stopped and the patient should be referred to an expert physician specialised or experienced in teratology for advice.	
Other Precautions	
I have explained the patient that Toctino has been prescribed to her only and must not be shared with others.	
I have explained the patient that she must not donate blood during treatment with Toctino and for one month after discontinuation due to the potential risk to the foetus of a pregnant transfusion recipient.	
Date	

Pregnancies occurring during treatment and within 1 month following discontinuation of treatment should be reported to the below contact details.

Neopharm will follow up with you to record the pregnancy outcome.

Reporting side effects

You can report side effects to the Ministry of Health (MoH) by following the link 'Reporting Side Effects of Medication' on the MoH home page (www.health.gov.il) which links to an online form for reporting side effects, or by clicking the link:
https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

You can also report directly to the Patient Safety Unit at Neophram:
drugsafety@neophamgroup.com Tel. 03-9373796 or 1-800-250-255

The format and content of this checklist were reviewed and approved by the Ministry of Health in October 2018.