



Pregnancy Prevention Program

Patient Information Brochure

This sheet contains important information about treatment with Toctino and the risk of birth defects when taking this medicine.

This information sheet is part of the pregnancy prevention program for Toctino. Before taking Toctino you are advised to read the entire information sheet carefully. This information sheet supplements the guidelines you will receive from your doctor or pharmacist, but does not replace them. Read the patient information leaflet before you use this medicine because it contains also important information about how to take this medicine, information about side effects, and special warnings. If you have any questions or concerns about taking Toctino, consult your doctor or pharmacist.

Information about birth defects

The active ingredient in Toctino is alitretinoin, which belongs to the retinoid group. Medicines in this group, including Toctino, are highly likely to harm unborn babies and cause severe birth defects even if only taken for a short period during pregnancy. Furthermore, Toctino increases the chance of miscarriage. So, you must follow all the instructions in the Toctino pregnancy prevention program that are listed below.

Important information for female patients

- Do not use Toctino if you are pregnant.
- You must not get pregnant during the course of treatment with Toctino and for one month after completing treatment with Toctino.
- If you think you might be pregnant despite using contraception, stop taking Toctino immediately and consult your doctor.
- This medicine has been prescribed specifically for you. Do not share this medicine with another person, particularly with another woman, even if he or she has the same medical problem that you have. Please return any unused medicines to the pharmacy.
- Do not donate blood during the course of treatment and for one month after ending your treatment, because the woman who gets this blood may be pregnant and her unborn baby may be exposed to the risk.
- You will be given your first prescription after you have had two negative pregnancy tests, conducted before starting treatment four weeks apart, or if your doctor can positively rule out the possibility of pregnancy (for example due to sterilization).
- If you are of child-bearing age and there is a chance that you will become pregnant, you will have to show a negative pregnancy test every month. After receiving a definite negative pregnancy test, you will be given a Toctino prescription for the following month.
- You will have a final pregnancy test 5 weeks after completing the treatment with Toctino.
- Talk to your doctor or gynecologist about effective contraceptives.
- You must use at least one contraception method, and preferably two contraception methods **for one month before starting this treatment, during the course of this treatment, and for a month after completing the treatment.**
- Because any contraceptive, including oral hormonal contraceptives (the Pill), may fail and allow you to get pregnant, it is better to use two different contraception methods. One main method (such as the Pill or some other hormonal contraceptive or an intrauterine device) together with a barrier method such as condoms, a diaphragm with spermicide, etc.
- **You must not take Toctino if you are breastfeeding** because Toctino may pass into your breast milk.

- Talk to your doctor if you are planning to take other medicines or herbal remedies, particularly if you are taking contraceptive pills or some other hormonal contraceptive.
- When your treatment is completed, return any unused medicines to your doctor or pharmacist.

Important information for male patients

- Do not donate blood during the course of treatment and for one month after ending your treatment. If a woman who receives your blood gets pregnant, her unborn baby is at high risk of developing birth defects. When your treatment is completed, return any unused medicines to your doctor or pharmacist.
- Do not share Toctino with another person, even if he or she has the same medical problem that you have.
- Studies have shown that a small amount of Toctino was present in sperm. These levels are considered too low to have an effect on your partner's unborn baby.
- Based on pre-clinical studies (animal studies), male fertility may be compromised by treatment with Toctino. However, in these studies no impact was observed on reproductive parameters even when using a high dose that resulted in blood concentrations of the medicine that are similar to those in humans.

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 Neopharm:

drugsafety@neophamgroup.com Tel. 03-9373796 or 1-800-250-255

The format and content of this card were reviewed and approved by the Ministry of Health in March 2017.



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