Pregnancy Prevention Program

Patient Information Brochure

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

This information brochure is part of the pregnancy prevention program for Toctino. Before taking Toctino you are advised to read the entire information brochure carefully. This information brochure 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 also contains 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 a negative pregnancy test, conducted before starting treatment, 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 one month after completing the treatment with Toctino.
- Talk to your doctor or gynecologist about effective contraception.
- You must use at least one very effective contraception method (such as an intrauterine device or implant) or correctly use two effective contraception methods that work differently (such as oral contraceptives together with a condom) before starting this treatment, during the course of this treatment, and for a month after stopping the treatment.
- Because any contraceptive method, including oral hormonal contraceptives (the Pill), may fail and allow you to get pregnant, it is preferable 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.

Patient Card

Patient Reminder Card

Doctor name:

Phone number:

Do not use Toctino when pregnant

If a pregnant woman takes Toctino it can be very harmful to her unborn baby.

If you are pregnant or think you might be pregnant, stop taking Toctino immediately and consult your doctor.

Read the package leaflet carefully before you start using this medicine.

If you have any questions or concerns about taking Toctino, consult your doctor or pharmacist.

What you need to do if you can possibly get pregnant:

- You must use at least one very effective contraception method (such as an intrauterine device or implant) or correctly use two effective contraception methods that work differently (such as oral contraceptives together with a condom) before starting this treatment, during the course of this treatment, and for a month after stopping the treatment.

- You must not get pregnant during the course of treatment with Toctino and for one month after stopping treatment with Toctino.

- You must go for routine follow-up tests and have regular pregnancy tests:

- Before you start treatment, you will have to have a pregnancy test and it must be negative.
- In order to make sure that you are not pregnant while taking this treatment, you will have to have regular pregnancy tests, ideally every month. In addition, you will have to have a final pregnancy test one month after stopping treatment.

Reminder to female and male patients:

This medicine has been prescribed specifically for you. Do not share this medicine with another person. **Please return any unused medicines to the pharmacy.**

Visits table

Use this table to record the dates of your visits to the doctor:

Doctor name:

Phone number:

Visit date	Contraceptives in use	Pregnancy test result	Doctor signature
		☐ Positive ☐ Negative Date:	
		☐ Positive ☐ Negative Date:	
		☐ Positive ☐ Negative Date:	
		☐ Positive ☐ Negative Date:	
		☐ Positive ☐ Negative Date:	
		☐ Positive ☐ Negative Date:	
		☐ Positive ☐ Negative Date:	

Reporting side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Medication' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this 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 card were reviewed and approved by the Ministry of Health in October 2018.

Pregnancy Prevention Program **Patient Information Brochure**