PREGNANCY PREVENTION PROGRAMME

Information brochure

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Toctino – What you need to know

Information brochure for patients

About this brochure

Your dermatologist has prescribed Toctino to you. This brochure contains important information about your treatment with Toctino and about the risk of possible birth defects when taking this medicine. It is part of the pregnancy prevention programme for Toctino. Please read this brochure carefully before taking Toctino to make sure that you know all important information relating to Toctino.

This guide is intended as an addition to, but not as a replacement for, your doctor's or pharmacist's instructions. Please read the whole brochure.

You will find further information about Toctino, including how to take the medicine, which side effects may occur and special warnings, in the Toctino patient information leaflet. Please also read and follow the instructions given in the patient information leaflet.

After reading this brochure, you should consult your doctor if you have any further questions or concerns about taking Toctino.

Severe chronic hand eczema and Toctino

Toctino is a medicine used to treat severe chronic hand eczema in adults and is taken by mouth. Severe chronic hand eczema is an inflammatory skin disease. This inflammation causes redness, blisters, skin dryness and peeling, cracking, itching and pain.

Toctino is only used to treat severe chronic hand eczema and is only prescribed if symptoms have not improved after topical treatments, including steroid (cortisone) ointments or gels. Treatment with Toctino continues until your hands are free, or almost free, of eczema, which can take up to six months. Toctino capsules are available in two strengths: 10 milligrams and 30 milligrams. At the beginning of your treatment with Toctino, you will be given the medicine in the 30-milligram strength. If this causes side effects, you may have to switch to the lower strength by consultation with your doctor.

Information about birth defects

Toctino belongs to a group of medicines known as retinoids, which are known to cause severe birth defects if used during pregnancy. This risk of birth defects is extremely high even if Toctino is taken only for a short time during pregnancy.

In addition, taking Toctino during pregnancy increases the risk of a miscarriage. For these reasons, women of childbearing potential are not allowed to use Toctino, unless all instructions described in the Pregnancy Prevention Programme are being followed.

Important information for female patients

- You must not take Toctino if you are pregnant.
- You must not get pregnant while you are taking Toctino and for one month after you stop taking Toctino.
- Your doctor will ask you to confirm in writing that you have been informed about the high risk of fetal birth defects for your baby if you become pregnant while taking Toctino or within 1 month after stopping treatment. You will also have to confirm that you understand and accept the need to use two effective and complementary methods of contraception without interruption for at least 1 month before starting treatment, during treatment, and for at least 1 month after treatment is stopped.
- You will get your first prescription for Toctino only after you have had at least two separate medically supervised pregnancy tests that show you are not pregnant or if there are legitimate medical reasons why you cannot get pregnant, e.g. if you have already gone through menopause.
- If you are at risk of becoming pregnant, you must have a medically supervised pregnancy test every month. Once the result of the pregnancy test confirms that you are not pregnant, the doctor will prescribe you Toctino for no more than 30 days of treatment. The last pregnancy test will take place one month after the end of treatment with Toctino.
- You must discuss effective methods of contraception with your gynaecologist. You must consistently and correctly use two effective and complementary methods of birth control at the same time without interruption for at least 1 month before starting treatment, during treatment, and for at least 1 month after stopping treatment. The two methods of birth control must include one primary method and a second, complementary method. Because each method can fail, including the oral contraceptives (the pill), the use of two methods together including a barrier method is required. Detailed information about the choice of effective methods can be found in the Contraception Information Brochure, which is also part of the pregnancy prevention programme. Your doctor will give you a copy of this brochure.

- Even if your menstrual period is irregular or missing, you must continue to strictly use the selected contraceptive methods during Toctino treatment. The same is true if you are currently sexually inactive.
- Stop taking Toctino and contact your doctor immediately if you have unprotected sex, miss your period, become pregnant, or suspect that you have become pregnant while you are taking Toctino or 1 month after stopping treatment. Signs and symptoms of a pregnancy may vary from individual to individual, but can include bleeding, breast pain, nausea and vomiting.
- Do not breastfeed during treatment with Toctino or for one month after you take Toctino for the last time because Toctino may pass into your breast milk and harm your baby.
- Talk to your doctor if you plan to take other medicines, whether bought over-the-counter or prescribed, or herbal products, particularly if you are taking birth control pills or other hormonal contraceptives. Certain medicines and herbal supplements, such as St. John's Wort, may make some methods of birth control less effective. You should avoid taking St. John's Wort during treatment with Toctino.
- Do not donate blood during treatment with Toctino or during the 1 month after stopping treatment. If a pregnant woman receives your blood, her unborn baby is at risk of severe birth defects.
- Do not share this medication with anyone else, particularly with female patients, even if they have the same condition as you.
- Return all unused Toctino to your doctor or your pharmacist at the end of treatment.

Important information for male patients

- Do not donate blood during treatment with Toctino or during the 1 month after stopping treatment. If a pregnant woman receives your blood, her unborn baby is at risk of severe birth defects.
- Do not share this medication with anyone else, particularly with female patients, even if they have the same condition as you.
- Return all unused Toctino to your doctor or your pharmacist at the end of treatment.
- Very low levels of alitretinoin are present in the semen of men taking Toctino. These levels are considered too low to harm the unborn baby of your female partner.

You will find further important information about Toctino, including how to take the medicine, which side effects may occur and special warnings, in the patient information leaflet. Please also read this carefully before you take the medicine for the first time and follow the instructions it contains. Please talk to your attending dermatologist if you still have unanswered questions or are uncertain about taking Toctino.

Doctor's stamp

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Toctino – Acknowledgement Form for Male Patients

Present to the patient for acknowledgement and signature.

Taking Toctino – even in small quantities – during pregnancy is associated with a high risk of malformations in the unborn child. In the following cases there is an extremely high risk of severe malformations in the child:
- If the woman is already pregnant when she starts treatment with Toctino
- If the woman becomes pregnant during treatment with Toctino
- If the woman becomes pregnant in the first 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 fully 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 have been specifically discussed and made clear to me:

1. I have been informed that Toctino belongs to a group of medicines (retinoids) known to cause severe birth defects if taken during pregnancy.
2. I have been informed that I must not donate blood during treatment with Toctino and for 1 month after stopping treatment with Toctino.
3. II have read and understood the following documents that I received from my doctor: *Patient Information Brochure*.
4. I understand that I must not share the medicine with other people, in particular women.
5. I understand that I must not dispose of the medicine down the drain or with household waste and that I must return unused or expired medicine to the pharmacy for disposal. I may only keep any unused capsules if my doctor gives me explicit permission to do so.

My doctor has answered all my questions about Toctino. All the relevant risks and precautions have been explained to me fully.

Patient's signature

Date Patient's name in block capitals

Acknowledgement Form for Female Patients

Present to the patient for acknowledgement and signature

Taking Toctino – even in small quantities – during pregnancy is associated with a high risk of malformations in the unborn child. In the following cases there is an extremely high risk of severe malformations in your child:
- If you are already pregnant when you start treatment with Toctino
- If you become pregnant during treatment with Toctino
- If you become pregnant in the first 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 fully understand in the information you have received about using Toctino.

My doctor has personally informed me about treatment with Toctino. The following points in particular have been explained and emphasised:

1. I have been informed that Toctino belongs to a group of medicines (retinoids) known to cause severe birth defects if taken during pregnancy.
2. I have been informed that I must not take Toctino if I am pregnant or could become pregnant.
3. I understand that, for at least one month before treatment, during treatment and for one month after the end of treatment, I need to use two effective, complementary methods of contraception* consistently and correctly.
4. I am fully aware of the risks of contraceptive failure, which my doctor has explained to me.
5. I understand that I may only take Toctino after a negative pregnancy test has confirmed with certainty that I am not pregnant.
6. I know that I need to take several pregnancy tests under medical supervision, including two tests at least three weeks apart before starting treatment, with the second test only being performed after I have used effective contraception for at least one month, and that I need to take a pregnancy test at every monthly checkup during treatment and one month after the last time I take Toctino.
7. I have read and understood the following documents that I received from my doctor: *Patient Information Brochure* and *Contraception Information Brochure*.
8. I agree to inform my doctor of any prescription or over-thecounter medicines or herbal products that I am planning to take during my treatment with Toctino given that certain types of medicines or herbal products (e.g. St. John's wort) may make hormonal forms of contraception (e.g. the pill) less effective.
9. I am aware of the fact that I must stop taking Toctino immediately and notify my doctor if I get pregnant, if my period is more than seven days late, if I stop using two methods of contraception or if I have unprotected sex during my treatment (and for one month after the end of treatment).
10. I understand that I need to notify the doctor who prescribed me Toctino if I get pregnant anyway. I understand that once I have immediately informed my doctor that I may be pregnant, I may be referred to a specialist in birth defects or a doctor with experience in this field.
11. I understand that I must not donate blood during my treatment with Toctino and in the one month after I have stopped taking Toctino.
12. I understand that I must begin each 30-day supply of Toctino within 7 days after my medically supervised negative pregnancy test.
13. I understand that I must not share the medicine with other people, in particular women.
14. I understand that I must not dispose of the medicine down the drain or with household waste and that I must return unused or expired medicine to the pharmacy for disposal. I may only keep any unused capsules if my doctor gives me explicit permission to do so.

* !You will find information about reliable contraception methods in the *Contraception Information Brochure* of the Toctino pregnancy prevention programme

My doctor has answered all my questions about Toctino. I understand that I am responsible for not getting pregnant for at least one month before treatment starts with Toctino, during treatment and for one month after the end of treatment and that I must therefore use two effective, complementary methods of contraception during this time. All the relevant risks and precautions have been fully explained to me.

Patient's signature

Date Date Patient's name in block capitals