

Checklist for Prescribing to Female Patients

Name of patient

To be kept with patient notes to document compliance
with the Pregnancy Prevention Programme

Toctino[®] (alitretinoin)

The active ingredient of Tocrino is alitretinoin. Alitretinoin belongs to a class of medicines (retinoids) known to cause severe birth defects. Foetal exposure to alitretinoin, even for short periods, presents a high risk of congenital malformations. Tocrino is therefore strictly contraindicated in women of childbearing potential, unless all conditions in the Pregnancy Prevention Programme are fulfilled.

As the prescribing doctor you should make sure that every action is taken to ensure that the risks and consequences are fully understood by all female patients before allowing them to start treatment (or continue treatment) with Tocrino.

Before initiating Tocrino therapy in a female patient of childbearing potential the following checklist should be completed and stored in the patient's notes. This checklist also includes a section for monitoring follow-up visits in patients at risk of pregnancy.

The checklist consists of 3 parts:

Part A – To be completed for all patients (page 4)

Part B – Women at risk of pregnancy (page 5)

Criteria for prescribing Tocrino in patients at risk of pregnancy (page 5)

Provision of information to patients at risk of pregnancy (page 6)

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Part C – Patients not at risk of pregnancy (page 10)

Provision of information to patients not at risk of pregnancy (page 10)

Acknowledgement Form for Female Patients (page 10)

This checklist should be used in conjunction with the following brochures:

- Guidance for Doctors and Pharmacists
- Doctor's Checklist for Prescribing to Female Patients (this document)
- Acknowledgement Form for Female Patients
- Patient Information Brochure
- Information About Contraception

Part A.

To be completed for all patients

Patient name: _____

Date of birth: _____ Hospital number: _____

A current sexual history should be taken for all females of childbearing potential. Although clinicians should be sensitive to issues of age, race or religious belief, no assumptions should be made on the basis of these factors.

It may be necessary to exclude parents and partners and interview the patient alone in order to obtain a complete sexual history. It must be determined whether the patient is at risk of pregnancy:

Is the patient at risk of pregnancy?

☐ Yes

☐ No

If yes, the patient is at risk of pregnancy, please proceed to part B.

If no, the patient is not at risk of pregnancy, please proceed to part C.

Part B. Women at risk of pregnancy

The Pregnancy Prevention Programme should be followed in all patients at risk of pregnancy. Specialist advice may be required for cases of women with irregular menses who present with difficult therapeutic management issues.

Criteria for prescribing Tactino in patients at risk of pregnancy

It is important to ensure that the following criteria are met.

1. Is the patient an adult with severe chronic hand eczema, unresponsive to treatment with potent topical steroids?	Yes	No
2. Does the patient understand the teratogenic risk of Tactino?	Yes	No
3. Does the patient understand the need for rigorous follow-up, on a monthly basis?	Yes	No
4. Does the patient understand and accept the need for effective contraception beginning 1 month before starting treatment and continuing without interruption throughout the course of treatment and for 1 month after the end of treatment?	Yes	No
5. Does the patient understand that at least one and preferably two complementary forms of contraception, including a barrier method, should be used?	Yes	No
6. Is the patient capable of complying with effective contraceptive measures?	Yes	No
7. If the patient is not menstruating, does she understand that unless she has had a hysterectomy, she must still follow all of the advice on effective contraception?	Yes	No
8. Has the patient been informed such that she understands the potential consequences of pregnancy and the need to rapidly seek medical attention if there is a risk of pregnancy?	Yes	No
9. Does the patient understand and accept the need to undergo pregnancy testing before, during and 5 weeks after the end of treatment?	Yes	No
10. Has the patient acknowledged that she has understood the risks and necessary precautions associated with the use of Tactino?	Yes	No

Provision of information to patients at risk of pregnancy

Patients at risk of pregnancy should be provided with the ‘Patient Information Brochure’ and the ‘Information About Contraception’ brochure.

11. Has the patient received the ‘Patient Information Brochure’?	Yes	No
12. Has the patient received the ‘Information About Contraception’ brochure?	Yes	No

Date received: _____

Contraception in patients at risk of pregnancy

An appropriately trained healthcare professional should give advice on adequate contraception; this will not necessarily be the dermatologist. As a minimum, female patients at risk of pregnancy must use at least one effective method of contraception.

The most effective contraceptive methods include depot injections, implants, intra-uterine devices containing copper or progestogens, combined contraceptive pills and patches when used carefully.

All patients should preferably use two forms of contraception that are complementary and include a barrier method. Barrier methods on their own are not recommended. Contraception should be continued for at least 1 month after stopping treatment with Tactino, even in patients with amenorrhoea, unless they have had a hysterectomy.

13. Has the patient received advice on adequate contraception?	Yes	No
14. Has the patient used continuous effective contraception for at least one month?	Yes	No

Acknowledgement Form for Female Patients

All female patients who are at risk of pregnancy should sign a form to indicate that they fully understand the risks of pregnancy, are not currently pregnant and have been using adequate contraception for 1 month before starting treatment, and that the responsibilities of the patient and doctor have been discussed. This should include the responsibility of the patient to consult their GP, dermatologist or pharmacist if they have knowingly had unprotected intercourse so that the possibility of using emergency contraception can be considered.

15. Has the patient signed the Acknowledgment Form for Female Patients?	Yes	No
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Pregnancy testing in patients at risk of pregnancy

Blood or urine may be used for pregnancy testing, provided the method has a minimum sensitivity of 25mIU/mL.

Prior to starting Tactino therapy:

All female patients at risk of pregnancy should have a medically supervised pregnancy test up to 3 days prior to the initial visit to the prescriber or during the consultation itself. A second medically supervised pregnancy test should be performed after the patient has been using effective contraception for at least 1 month. This should ensure the patient is not pregnant when she starts treatment with Tactino.

16. Is the initial pregnancy test prior to starting Tactino therapy positive? Date of pregnancy test _____	Yes*	No
17. Is the second pregnancy test prior to starting Tactino therapy positive? Date of pregnancy test _____	Yes*	No

*** If the pregnancy test is positive Tactino should not be started.**

Starting Tactino therapy

Treatment should begin on the day that Tactino is dispensed to the patient and this should be within 7 days of visiting the prescriber and having a negative pregnancy test. Prescriptions of Tactino should be limited to 30 days of treatment and any continuation of treatment requires a new prescription. Ideally, pregnancy testing, issuing and dispensing of a Tactino prescription should occur on the same day. Dispensing of Tactino should occur within a maximum of 7 days of the prescription.

Follow-up visits

Follow-up visits should be arranged at 28 day intervals. Medically supervised pregnancy testing should be repeated where necessary after consideration of the patient's sexual activity and recent menstrual history (abnormal menses, missed periods or amenorrhoea). Where indicated, follow-up pregnancy tests should be performed on the day of the prescribing visit or in the 3 days prior to the visit to the prescriber.

18. Record of pregnancy testing on follow-up visits where necessary		
Follow-up visit 1: Is the pregnancy test positive? Date of pregnancy test _____	Yes*	No
Follow-up visit 2: Is the pregnancy test positive? Date of pregnancy test _____	Yes*	No
Follow-up visit 3: Is the pregnancy test positive? Date of pregnancy test _____	Yes*	No
Follow-up visit 4: Is the pregnancy test positive? Date of pregnancy test _____	Yes*	No
Follow-up visit 5: Is the pregnancy test positive? Date of pregnancy test _____	Yes*	No
Follow-up visit 6: Is the pregnancy test positive? Date of pregnancy test _____	Yes*	No
Follow-up visit 7: Is the pregnancy test positive? Date of pregnancy test _____	Yes*	No
Follow-up visit 8: Is the pregnancy test positive? Date of pregnancy test _____	Yes*	No
Follow-up visit 9: Is the pregnancy test positive? Date of pregnancy test _____	Yes*	No
Follow-up visit 10: Is the pregnancy test positive? Date of pregnancy test _____	Yes*	No

*** If pregnancy occurs in a woman treated with Tactino, treatment must be stopped and the patient should be referred to a physician specialised or experienced in teratology for advice.**

The results of pregnancy tests at any additional follow-up visits should also be recorded.

End of treatment

Five weeks after stopping treatment, women should undergo a final pregnancy test to exclude pregnancy.

19. Is the pregnancy test 5 weeks after stopping Tactino treatment positive? Date of pregnancy test _____	Yes*	No
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*** If pregnancy occurs in a woman within 5 weeks of stopping Tactino treatment, the patient should be referred to a physician specialised or experienced in teratology for advice.**

Part C.

Patients not at risk of pregnancy

Discussion of the risks of becoming pregnant whilst taking Tactino should not be limited to those who are sexually active before treatment starts. A patient's sexual behaviour may change during therapy.

1. Does the patient understand the teratogenic risk of Tactino?	Yes	No
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Provision of information to patients not at risk of pregnancy

Patients not at risk of pregnancy should be provided with the 'Patient Information Brochure' and the 'Information About Contraception' brochure.

2. Has the patient received the 'Patient Information Brochure'?	Yes	No
3. Has the patient received the 'Information About Contraception' brochure?	Yes	No

Date received: _____

Acknowledgement Form for Female Patients

All female patients, even those not at risk of pregnancy, should sign a form confirming that they fully understand the risks of pregnancy, that they are not currently pregnant, and that the responsibilities of the patient and doctor have been discussed. This should include the responsibility of the patient to consult their GP, dermatologist or pharmacist if they have knowingly had unprotected intercourse so that the possibility of using emergency contraception can be considered.

4. Has the patient signed the Acknowledgement Form for Female Patients?	Yes	No
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