Prescriber Checklist/Acknowledgement Form for Prescribing Neotigason (acitretin) to Female Patients

The potential for pregnancy must be assessed for all female patients prescribed acitretin.

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

Acitretin belongs to the retinoid class of drugs that cause severe birth defects. Foetal exposure to acitretin, even for short periods, presents a high risk of congenital malformations. Acitretin is therefore strictly contraindicated in women of childbearing potential, unless all conditions in the Acitretin Pregnancy Prevention Programme are fulfilled.

As the prescribing doctor, you must make sure that the risk of serious harm from drug exposure during pregnancy is fully understood by all female patients before treating them with acitretin.

Before initiating acitretin 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.

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Please report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme. You can report via:

- the Yellow Card website, www.mhra.gov.uk/yellowcard
- the free Yellow Card app available from the
  - → Apple App Store or Google Play Store
  - → some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours.

When reporting please provide as much information as possible. By reporting side effects, you can help provide more information on the safety of this medicine.

Adverse events may also be reported to Teva UK Limited via email to medinfo@tevauk.com or via phone on +44 (0) 207 540 7117.

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Is the patient a woman of childbearing potential? Yes/No

If 'No' go to section 4.

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**, acitretin must not be prescribed.

	Doctor confirm: I have explained this to my patient [YES/NO]	Patient confirm: I have understood this [YES/NO]
Is the patient suffering from a severe extensive refractory form of psoriasis, palmoplantar pustular psoriasis, severe congenital ichthyosis and ichthyosiform dermatitis, lichen ruber planus of skin and mucous membranes, other severe and refractory forms of dermatitis characterised by dyskeratosis and/or hyperkeratosis.		
1. Teratogenicity		
The patient understands that acitretin belongs to a class of drugs (retinoids) known to cause severe birth defects and that they must not get pregnant whilst taking it. Acitretin also increases the risk of miscarriage when taken during pregnancy.		
2. Contraception		
The patient understands that she must consistently and correctly use at least 1 highly effective method of contraception (i.e. a user-independent form such as an intrauterine device or implant) or 2 complementary methods of birth control (i.e. userdependent forms such as oral contraceptive and barrier method) before and during treatment.		
The patient understands that the risk persists even after the medication is stopped and that she must not get pregnant within 3 years 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.		
3. Pregnancy Testing & Monthly Prescriptions		
The first prescription for acitretin 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.		
Patient understands that in order to support regular follow up, including pregnancy testing and monitoring, ideally the prescription should be limited to 30 days.		
Patient understands the need for and agrees to pregnancy testing before, during and after treatment.		
Patient understands the need for periodic pregnancy tests with 1-3 monthly intervals throughout treatment and also for a period of 3 years after stopping treatment. This is because the drug can stay in the body for 3 years after the last dose and can damage an unborn baby if pregnancy occurs.		
The contraceptive methods and pregnancy test results should be recorded in the patient's medical records.		
The patient has received a copy of the educational package.		
The patient knows to contact their doctor if they have unprotected sex, miss their period, become pregnant, or suspect that they have 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.		
4. Other Precautions		
Patient understands that acitretin has been prescribed to her only and must not be shared with others.		
Patient understands that she must not donate blood during treatment with acitretin and for 3 years after discontinuation due to the potential risk to the foetus of a pregnant transfusion recipient.		
Doctor Signature		
Patient Signature*		
Date		

*Signature of parent or legal guardian is necessary if the patient is under the age of 18

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