Ireland
Teva Pharmaceuticals Ireland

Actavis

Physician Checklist/ Acknowledgement Form

for Prescribing Neotigason▼(acitretin) to Female Patients

The potential for pregnancy must be assessed for all girls and women of childbearing potential prescribed Neotigason.

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

A woman of childbearing potential is defined as a pre-menopausal female who is capable of becoming pregnant

This form is to be completed by the physician and patient at initial and follow-up visits for all female patients prescribed Neotigason. The signed document should be kept with the patient notes to document compliance with the Neotigason Pregnancy Prevention Programme. **After completion a copy of this document should be given to the patient.**

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

As the prescribing doctor, you must ensure that the teratogenic risk and necessary precautions are fully understood by all female patients before treating them with Neotigason. **Please use the patient reminder card to support your discussion with the patient.**

Women of childbearing potential

Review the statements in Part A (physician checklist) and Part B (patient checklist) overleaf, discuss them with your patient and ensure that she understands and acknowledges the risks and necessary precautions related to the use of Neotigason.

Record confirmation of this on the form. If the answer to any of these questions is NO, Neotigason must not be prescribed.

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Doctor Part A

	Doctor confirm: I have discussed this with my patient [YES/NO]
I confirm that the patient is prescribed Neotigason because she is suffering from: severe extensive psoriasis which is resistant to other forms of therapy, palmo-plantar pustular psoriasis, severe congenital ichthyosis, severe Darier's disease (keratosis follicularis) or severe lichen planus.	YES ☐ NO ☐
Teratogenicity	
Neotigason belongs to a class of drugs (retinoids) known to cause severe and serious foetal malformations, including central nervous system abnormalities, facial dysmorphia, cleft palate, external ear abnormalities, eye abnormalities, cardiovascular abnormalities, thymus gland abnormality and parathyroid gland abnormalities.	YES ☐ NO ☐
Neotigason increases the risk of spontaneous abortion when taken during pregnancy.	YES ☐ NO ☐
Neotigason must not be used in pregnancy.	YES ☐ NO ☐
Contraception	
The need for consistent and correct use, without interruption, of at least 1 highly effective method of contraception (i.e. a user-independent form such as an intra-uterine device or implant) or 2 complementary user-dependent methods of contraception (e.g. oral contraceptive and barrier method).	YES ☐ NO ☐
The need for contraception, as described above, for at least 1 month before treatment, throughout the entire duration of treatment and for at least 3 years after stopping treatment as the risk persists until the product is completely eliminated, which is within 3 years following the end of treatment.	YES ☐ NO ☐
I have provided advice on contraception which is appropriate for the patient or I have referred her for contraceptive services as appropriate for her.	YES ☐ NO ☐
Pregnancy Testing & Monthly Prescriptions	
The need for a medically supervised pregnancy test at least one month after the patient has started using contraception and shortly (preferably a few days) prior to the first prescription for Neotigason to ensure that the patient is not pregnant when she starts treatment.	YES ☐ NO ☐
The need for prescriptions to ideally be limited to 30 days, in order to support regular follow up, including pregnancy testing and monitoring.	YES ☐ NO ☐
The need for pregnancy testing during (ideally monthly) and periodically with 1-3 monthly intervals for a period of 3 years after stopping treatment, as the risk of severe and serious foetal malformations persists until the product is completely eliminated.	YES ☐ NO ☐
The need to contact her doctor immediately in case of suspected or inadvertent pregnancy during treatment or within 3 years after stopping treatment.	YES ☐ NO ☐
The need to stop treatment immediately in case of suspected or inadvertent pregnancy and need for patient referral to an expert physician specialised or experienced in teratology for advice (in case of pregnancy).	YES ☐ NO ☐
I have provided the patient with a copy of the patient reminder card.	YES ☐ NO ☐
Other Precautions	
Neotigason must not be shared with others.	YES ☐ NO ☐
The patient must not donate blood during treatment with Neotigason and for 3 years after discontinuation due to the potential risk to the foetus of a pregnant transfusion recipient.	YES ☐ NO ☐

Doctor name: _____

Doctor Signature: _____ **Date:** _____

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Patient Part B

	Patient confirm: The doctor has explained the following information and I confirm that I have understood it **[YES/NO]**
Why I have been prescribed Neotigason.	YES ☐ NO ☐
Teratogenicity	
That Neotigason can seriously harm an unborn baby (the medicine is said to be 'teratogenic'). It can cause serious abnormalities of the unborn baby's brain, face, ear, eye, heart and certain glands (thymus gland and parathyroid gland).	YES ☐ NO ☐
That Neotigason also makes a miscarriage more likely even if only taken for a short time during pregnancy.	YES ☐ NO ☐
That I must not take Neotigason if I am pregnant or think I might be pregnant.	YES ☐ NO ☐
Contraception	
That I must use at least 1 very reliable method of contraception (for example an intra-uterine device or implant) or 2 effective methods that work in different ways (for example a hormonal contraceptive pill and a condom).	YES ☐ NO ☐
That I must use contraception as described above for 1 month before taking Neotigason, during treatment and for 3 years after stopping treatment, as some medicine may still be left in my body after stopping treatment.	YES ☐ NO ☐
We discussed the possibilities of effective contraception, or we planned a consultation with a professional experienced in advising on effective contraception.	YES ☐ NO ☐
Pregnancy Testing & Monthly Prescriptions	
That my doctor will ask me to take a pregnancy test before I start treatment. The test must show that I am not pregnant when starting treatment with Neotigason.	YES ☐ NO ☐
That the prescription is limited to 30 days in order to support regular follow up, including pregnancy testing and monitoring.	YES ☐ NO ☐
The need for pregnancy testing during (ideally monthly) and every 1-3 months for a period of 3 years after stopping treatment, because some medicine may still be left in my body and could damage an unborn baby if pregnancy occurs.	YES ☐ NO ☐
The need to contact my doctor immediately if I have unprotected sex, miss a period, am pregnant, or think that I might be pregnant while taking Neotigason or within 3 years after stopping treatment.	YES ☐ NO ☐
The need to stop taking Neotigason straight away if I become pregnant or think I might be pregnant. That my doctor may send me to a specialist for advice.	YES ☐ NO ☐
I have received a copy of the patient reminder card.	YES ☐ NO ☐
Other Precautions	
That I must not share this medicine with others.	YES ☐ NO ☐
That I must not donate blood during treatment with Neotigason and for 3 years after stopping treatment because an unborn baby could be harmed if a pregnant woman receives my blood.	YES ☐ NO ☐

Patient name: _____

Patient Signature*: _____ **Date:** _____

*** Signature of parent or legal guardian is necessary if the patient is under the age of 16.**

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Reporting suspected adverse events or reactions

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. Reporting forms and information can be found at www.hpra.ie.

Adverse events should also be reported to Teva by telephone (00442075407117) or email (safety.ireland@teva.ie).

Pregnancies occurring during treatment and within 3 years following discontinuation of treatment should be reported to the MAH at Teva Pharmacovigilance, contact details as above, who will follow up with you to record the pregnancy outcome.

- **For additional hard copies of this risk minimisation material** please contact our Teva Ireland Customer Service number on Freephone 1800-201-700.
- **For additional electronic copies of this risk minimisation material,** refer to www.hpra.ie and download the required material (enter 'Neotigason' or 'acitretin' in the search box and click on 'EdM' next to any of the medicines that appear).

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