

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.

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 met.

As the prescribing doctor, you must ensure that the teratogenic risk and necessary precautions are fully understood and complied with 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.

Doctor Part A

Doctor confirm:
I have discussed this with
my patient [YES/NO]

The patient is a female of childbearing potential

YES NO

I confirm that the patient is prescribed Neotigason because she is suffering from: severe intractable psoriasis in all its forms or severe forms of disorders of keratinisation, such as hyperkeratosis palmaris et plantaris, pustulosis palmaris et plantaris, ichthyosis, keratosis follicularis (Darier's disease), lichen planus affecting the skin or the mucosae or pityriasis rubra pilaris.

YES NO

Teratogenicity

Neotigason belongs to a class of drugs (retinoids) known to be highly teratogenic, including a high frequency of severe and life threatening birth defects (e.g., craniofacial defects, cardiac and vascular or CNS malformations, skeletal and thymic defects). Fatalities related to some of these malformations have been reported.

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 effective contraception, 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 combination hormonal contraceptive product and barrier method, such as a condom or diaphragm). Low dose progesterone-only products (minipills) are not recommended due to indications of possible interference with their contraceptive effect.

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 oral and written 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 (minimum sensitivity of 25 mUI/mL) at least one month after the patient has started using contraception and 3 days prior to the first prescription for Neotigason to ensure that the patient is not pregnant when she starts treatment.

YES NO

The need to begin therapy only on the second or third day of the next normal menstrual period.

YES NO

During therapy, the need for documented results of pregnancy tests every 28 days and a negative pregnancy test to be not older than 3 days before prescriptions are written.

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 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 is contraindicated while breastfeeding.

YES NO

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: _____

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), which can be fatal.

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 combination 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 in the 3 days before 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 documented pregnancy testing every 28 days during treatment 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 breastfeed while taking Neotigason.

YES

NO

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

Doctor name: _____

Patient Signature*: _____ Date: _____

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

Reporting suspected adverse events or reactions

Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems to allow continued monitoring of the benefit-risk balance of the medicinal product.

PBS Information: Authority Required (STREAMLINED).
Refer to PBS for full authority information.



Before prescribing, please review the full product information by scanning the QR code.

Teva Pharma Australia Pty Limited

Level 1, 37 Epping Rd
Macquarie Park, NSW, 2113

1800 288 382

www.tevapharma.com.au