

Neotigason Pregnancy Prevention Programme

Physician Checklist /Acknowledgement Form for Prescribing to Female Patients

The potential for pregnancy must be assessed for all female patients prescribed **NEOTIGASON (acitretin)**

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

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 postmenopause 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 **NEOTIGASON (acitretin)** and kept with patient notes to document compliance with the **NEOTIGASON (acitretin)** Pregnancy Prevention Programme. After completion a copy of this document should be given to the patient.

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

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

Before initiating **NEOTIGASON (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.

Women with 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**, **NEOTIGASON (acitretin)** must not be prescribed.

	Doctor confirm: I have explained this to my patient [YES/NO]
Is the patient suffering from a severe form of acne, severe form of psoriasis or severe disorder of keratinisation which is resistant to standard therapies?	explained: yes <input type="checkbox"/> no <input type="checkbox"/>
The patient understands that NEOTIGASON (acitretin) belongs to a class of drugs (retinoids) known to cause severe birth defects and that they must not get pregnant whilst taking it. NEOTIGASON (acitretin) also increases the risk of miscarriage when taken during pregnancy.	explained: yes <input type="checkbox"/> no <input type="checkbox"/>
The patient understands the need for effective contraception, without interruption, 1 month before starting treatment, throughout the entire duration of treatment and for 3 years after the end of treatment.	explained: yes <input type="checkbox"/> no <input type="checkbox"/>
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.	explained: yes <input type="checkbox"/> no <input type="checkbox"/>
The patient has received advice on contraception which is appropriate for her and has committed to using it throughout the risk period.	explained: yes <input type="checkbox"/> no <input type="checkbox"/>
The patient is aware of the risk of contraceptive failure.	explained: yes <input type="checkbox"/> no <input type="checkbox"/>
The first prescription for NEOTIGASON (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.	explained: yes <input type="checkbox"/> no <input type="checkbox"/>
Patient understands that in order to support regular follow up, including pregnancy testing and monitoring, ideally the prescription should be limited to 30 days.	explained: yes <input type="checkbox"/> no <input type="checkbox"/>
Patient understands the need for and agrees to pregnancy testing before, during and after treatment.	explained: yes <input type="checkbox"/> no <input type="checkbox"/>
The patient understands the need and accepts to undergo regular pregnancy testing before, <u>ideally monthly during treatment and periodically with 1-3 monthly intervals for a period of 3 years after stopping treatment.</u>	explained: yes <input type="checkbox"/> no <input type="checkbox"/>
The patient was advised that the Patient Reminder Card was included in the product package.	explained: yes <input type="checkbox"/> no <input type="checkbox"/>
The patient knows to contact her doctor if she has unprotected sex, misses her period, becomes pregnant, or suspects she has become pregnant during the risk period.	explained: yes <input type="checkbox"/> no <input type="checkbox"/>
If pregnancy occurs, treatment must be stopped and the patient should be referred to an expert physician specialised or experienced in teratology for advice.	explained: yes <input type="checkbox"/> no <input type="checkbox"/>
Patient understands that NEOTIGASON (acitretin) has been prescribed to her only and must not be shared with others.	explained: yes <input type="checkbox"/> no <input type="checkbox"/>
Patient understands that she must not donate blood during treatment with NEOTIGASON (acitretin) and for 3 years after discontinuation due to the potential risk to the foetus of a pregnant transfusion recipient.	explained: yes <input type="checkbox"/> no <input type="checkbox"/>

Date:

Pregnancies occurring during treatment and within 3 years following discontinuation of treatment should be reported to Teva Israel, the MAH, at safety.israel@teva.co.il, who will follow up with you to record the pregnancy outcome.



www.teva.co.il

להתוויית ולמידע נוסף אודות התכשיר כגון: תופעות לוואי, יש לעיין בעלון העדכני כפי שאושר ע"י משרד הבריאות.