Patient Guide: Neotigason (acitretin)
10 mg and 25 mg hard capsules

Pregnancy and Foetal Exposure Prevention
What this brochure is for

This brochure contains important information, especially for women of child-bearing age, as the risk of birth defects is high if Neotigason is taken during pregnancy or for a period after treatment has finished. Please read this brochure carefully before you start taking Neotigason.

Severe birth defects have occurred in babies of women taking acitretin in any amount – even for short periods – during pregnancy. These include serious central nervous system and heart defects; hearing and visual impairment; malformed ears; facial abnormalities such as high palate; malformations of bones and abnormalities of the thymus. There is also an increased risk of miscarriage.

Important information for women taking Neotigason

Neotigason contains the active ingredient acitretin, which causes severe birth defects in pregnancy and is also slowly removed from the body. Therefore if you are a woman of child-bearing age, you must not be or become pregnant during treatment or for 3 years after stopping treatment.

Adequate contraception is essential

- Discuss suitable, effective and ongoing contraception with your doctor.
- Any contraceptive method can fail – therefore you must use two effective forms of contraception at the same time. At least one of the methods must be a primary method
  - Primary methods include: intrauterine devices, injectable/implantable/insertable hormonal contraceptive products, oral contraceptives (the pill) and contraceptive patches when used carefully, tubal ligation, partner’s vasectomy.
  - Barrier methods include: male condom, diaphragm/cap with spermicide.
- Low-dose progesterone-only contraceptives ("minipills") are not recommended.
- You must have been using contraceptives at least 4 weeks before starting treatment with Neotigason.
- Use your contraception continuously. Do not stop using contraceptives at any point during treatment with Neotigason.
- You must not get pregnant for three years after stopping treatment. Therefore, you must continue to use the recommended contraceptives for 3 years after you have finished treatment with Neotigason.

Regular pregnancy testing

To make sure you are not pregnant during treatment, your doctor will carry out a pregnancy test before treatment starts with Neotigason.

As Neotigason treatment should be started on the second or third day after a normal menstrual cycle the pregnancy test should not be done earlier than 3 days before start of treatment. Before each month renewal of Neotigason prescription, your doctor will also want you to have a pregnancy test.
After completion of treatment, you will need to have a pregnancy test every 1-3 months for a period of 3 years.

**If you become pregnant during or after treatment**
If you have unprotected sex or miss your period while you are taking Neotigason or in the 3 years after you have stopped treatment, stop taking Neotigason (if treatment is still ongoing) and contact your doctor immediately.

If despite precautions, you become pregnant during treatment or within the 3 years after stopping Neotigason, the risk of extremely severe foetal malformations in the unborn baby is high. If you become pregnant during treatment stop taking Neotigason immediately. Contact your prescribing doctor or your nearest healthcare centre without delay for support and advice.

**Do not breast-feed during Neotigason treatment**
Do not take Neotigason if you are breast-feeding. Neotigason can pass into breast milk and may harm the baby.

**Avoid alcohol**
If alcohol is taken during treatment with Neotigason, a compound called etretinate can form which is removed very slowly from the body and can make the risk of birth defects last longer than 3 years. Therefore women of child-bearing age must not consume alcohol and should avoid all products containing alcohol (drinks, foods, and medicines) during treatment and for 2 months after stopping treatment.

**Prescription is only valid for 7 days**
Please use your prescription to collect your supply of Neotigason within seven days from the date written on the prescription. The pharmacy will not dispense your prescription beyond this seven-day deadline.

All of the above mentioned precautions must be followed, even if you are not sexually active, have amenorrhoea (you do not have menstrual periods) or are infertile (except in cases when the uterus has been removed (hysterectomy)).

**Acknowledgement form**
Your doctor will ask you to read and sign an ‘Acknowledgement Form for Female Patients’ to show that you understand the serious risks associated with acitretin and the preventive measures that need to be taken.

**Important information for men taking Neotigason**
Studies have shown that acitretin therapy does not influence the formation and quality of sperm. Acitretin and its metabolites are present at very low levels in your semen. These levels are considered too low to harm the unborn baby of your female partner.

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**Acitretine 10mg and 25mg Capsule, hard Patient guide Ireland**

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Important information for both women and men taking Neotigason

Giving blood during Neotigason treatment

Neotigason is carried in the blood. Neotigason in blood transfusions might harm unborn babies if given to pregnant women. Therefore both women and men treated with Neotigason must not give blood during treatment and for three years after completion of treatment.

Other medicines or herbal products

Talk to your doctor if you plan to take other medicines or herbal products. This is especially important for women using contraceptive pills and other types of hormonal contraceptives. Certain medicines and herbal supplements may make contraceptives less effective.

This medicine has been prescribed only for your personal use

You should never give this medicine to anyone else. Doing so can cause harm to unborn babies or other serious health problems. You should return any unused or expired medicines to the pharmacy for disposal.

Acknowledgement form

Your doctor will ask you to read and sign an acknowledgement form to show that you understand the serious risks associated with acitretin and the preventive measures that need to be taken.

Other information

While this brochure gives important facts about Neotigason that you need to be aware of, it does not replace the advice given to you by your dermatologist, doctor or pharmacist.

Further information (such as how to take Neotigason, special warnings and possible side effects) is included in the patient information leaflet, which is supplied in each pack of Neotigason. Please read this leaflet carefully.

If you have any further questions or concerns about taking Neotigason after you have read this brochure, talk to your dermatologist/doctor.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2; Tel;+3531 6764971; Fax:+3531 6762517. Website: www.hpra.ie; E-mail:medsafety@hpra.ie By reporting side effects you can help provide more information on the safety of this medicine.