# Neotigason® 25mg capsules

(acitretin)

## Patient Information Leaflet

**Please read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**
* Keep this leaflet. You may need to read it again.
* If you have any further questions, ask your doctor or pharmacist.
* This medicine has been prescribed for you only. Do not pass it on to others. It may harm them even if their signs of illness are the same as yours.
* If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**In this leaflet:**



## 1 What Neotigason is and what it is used for

Neotigason contains a medicine called acitretin. This belongs to a group of medicines called 'retinoids'.

Neotigason is used to treat severe skin problems where the skin has become thick and may be scaly. These skin problems include psoriasis, ichthyosis and keratosis follicularis (Darier's disease). It works by making your skin grow more normally.
Neotigason is normally used while under the care of a specialist dermatologist (skin doctor).

You must talk to a doctor if you do not feel better or if you feel worse.

## 2 What you need to know before you take Neotigason

**Do not take Neotigason if you:**
* **are pregnant, think you may be pregnant or if you might get pregnant while taking Neotigason or within 3 years of stopping it.** Pregnancy prevention measures are necessary, see section on 'Pregnancy and breast-feeding';
* are allergic (hypersensitive) to acitretin or any of the other ingredients of Neotigason listed in section 6 'Contents of the pack and other information', or if you take other 'retinoid' medicines, these include isotretinoin and tazarotene;
* are breast-feeding;
* have severe liver problems;
* have severe kidney problems;
* have very high levels of fat (lipids) in your blood;
* are taking medicines called tetracyclines (to treat infection) or methotrexate (for skin problems, Arthritis or cancer), see section on 'Taking other medicines';
* are taking Vitamin A, see section on 'Taking other medicines'.

Talk to your doctor before taking Neotigason, if you think any of the above might apply to you.

**Warnings and precautions**
* if you have diabetes. You will need to check your blood sugar levels more often when you start taking Neotigason;
* if you have high levels of fat in your blood or if you are obese. Your doctor may need to do blood tests while you are taking Neotigason to check the amount of fat in your blood;
* if you have heart problems. Your doctor may need to observe you more often e.g. to measure the blood pressure;
* if you drink a lot of alcohol;
* if you have liver problems;

Other things to consider while taking Neotigason:
* Neotigason can cause decreased night vision; (see 'Driving and using machines' in this section and also section 4);
* Neotigason can cause increased blood pressure in the skull, which should be checked as soon as possible by your doctor. For symptoms, see section 4;
* Neotigason can make the effects of UV light on the skin stronger. Before going out into strong sunlight apply a sunblock (with protection factor of at least SPF 15) to exposed skin. Unsupervised use of sun lamps and excessive exposure to sunlight should be avoided.
* Your liver function and fat (lipids) levels in your blood should be checked before starting treatment and then regularly during treatment. Your doctor may also periodically monitor your bones, as Neotigason may cause bone changes, especially in children and elderly receiving long-term treatment.
* High dose treatment with neotigason can cause mood changes (including irritability, aggression and depression);
* A serious conditions which causes the small blood vessels (capillaries) to leak has been reported very rarely (Capillary Leak Syndrome / Retinoic Acid Syndrome). This can lead to severe hypotension (low blood pressure), oedema (build up of fluid leading to swelling) and shock (collapse). See further in section 4.
* A serious skin reaction with symptoms such as rash, blistering or peeling of the skin (Exfoliative dermatitis) has been reported very rarely. See further in section 4.

**Women of childbearing potential:** Neotigason causes malformation in an unborn child. Pregnancy prevention measures and pregnancy tests are necessary during treatment and for 3 years after completion of treatment with Neotigason, see also section 'Pregnancy and breast-feeding'. Women of child-bearing potential may not consume alcohol during and for 2 months after stopping treatment, see section "Neotigason with alcohol".

**Blood donation:** You must not give blood while you are taking Neotigason and for 2 years after you stop taking it. This is due to the high risk of Neotigason causing malformation in an unborn child. Women of childbearing potential must therefore not receive blood from patients who are or have been treated with Neotigason within 2 years.

If any of the above apply to you, or if you are not sure, talk to your doctor or pharmacist before you take Neotigason.

Due to the risk of foetal malformations, the medicine must not be passed on to other people. Unused or expired products should be returned to a pharmacy for disposal.

It should be emphasized that currently, all the effects of life-long use of acitretin are not known.

**Other medicines and Neotigason**
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Methotrexate (for skin problems, arthritis or cancer), tetracyclines (to treat infections) or Vitamin A and other retinoids (such as isotretinoin and tazarotene) may not be used concurrently with Neotigason, see also section 'Do not take Neotigason'.

Tell your doctor in case you are taking phenytoin (to treat epilepsy) or low dose progesterone only contraceptives ('minipills') before starting treatment with Neotigason.

**Neotigason with alcohol**
Women of childbearing potential should not consume alcohol (in drinks, food or medicines) during treatment with Neotigason and for 2 months after cessation of therapy. Concurrent ingestion of acitretin and alcohol may result in formation of a compound (etretinate), which may be harmful to an unborn child, and if formed it takes a rather long time for it to be totally excreted from the body.

**Pregnancy, breast-feeding and fertility**
Do not take Neotigason if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Neotigason causes malformation in an unborn child. The following **instructions must be strictly followed**, even if you have fertility problems:

**WARNING TO FEMALE PATIENTS:**

> Neotigason will damage an unborn baby. **You must not take** Neotigason if you are pregnant, or think you may be pregnant. You must use effective birth control for one month before treatment, during treatment and for at least three years after treatment ends. Continue birth control methods until you have seen your dermatologist.

**Birth Control:** If you are a female at an age where you could get pregnant, **you must use an effective birth control (contraception)** without an interruption for at least 4 weeks before you start taking Neotigason, while you are taking it, and for 3 years after you stop taking it. Primary contraceptive method is a combination hormonal contraceptive product or an intrauterine device and it is recommended that a condom or diaphragm (cap) is also used. Low dose progesterone only contraceptives ('minipills') are not recommended as this type of contraceptive may be inadequate.

**Pregnancy tests:** Your doctor will want you to **have a pregnancy test** up to 3 days before starting treatment, which must be negative. Start taking Neotigason after the negative pregnancy test, on the second or third day of your next menstrual period.
You will also be asked to have **regular pregnancy tests** at 28 days intervals while you are taking Neotigason. Before each renewal of Neotigason prescription, your doctor will want you to have a negative pregnancy test. The test should not be older than 3 days.
After stopping the treatment with neotigason, pregnancy tests should be performed at 1-3 monthly intervals for a period of 3 years after last dose is given.

While you are taking Neotigason and for 3 years after stopping it, **contact your doctor immediately if you get pregnant or think you may be pregnant.**

If you have any question about these instructions, talk to your doctor or pharmacist before taking Neotigason.

**Driving and using machines**
Your vision may be affected, particularly at night time, while you are taking Neotigason. Be careful if you are driving or using any tools or machines.

**Neotigason contains:**
Contains glucose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

# Neotigason® 25mg capsules

(acitretin)

**Patient Information Leaflet (continued)**

## 3 How to take Neotigason

Always take Neotigason exactly as your doctor has told you. You should check with your doctor if you are not sure. The capsules should preferably be taken once daily with a meal or a drink of milk.

The usual starting dose for adults and elderly people is 25 mg (i.e. 1 capsule containing 25 mg acitretin) or 30 mg (i.e. 3 capsules each containing 10 mg acitretin).

Your doctor may adjust the dose depending on your disease and other factors e.g. your general health. The maximal recommended daily dose is 75 mg (i.e. 3 capsules each containing 25 mg acitretin).

**Women of child-bearing potential**
Start taking Neotigason on the second or third day of you next menstrual period. See section 2: (Warning to female patients)

**Use in children**
Children should only be given Neotigason when all other treatments have not cured the illness effectively. The doctor will decide the dose, which depends on the child's bodyweight. It is important to monitor a child's growth as dose is weight dependent.

**If you take more Neotigason than you should**
If you take more Neotigason than you should or if someone else takes your medicine, contact a doctor or hospital straight away. Symptoms of overdose are i.e. headache, dizziness, feeling or being sick, being sleepy or irritable or having itchy skin.

**If you forget to take Neotigason**
Take Neotigason as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Neotigason**
Do not stop taking Neotigason without consulting your doctor.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

## 4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Stop taking Neotigason and see a doctor immediately if you get the following side effects:**
- Severe headache, nausea, vomiting and visual disturbances. These may be symptoms of increased blood pressure in the skull (*very rare - may affect up to 1 in 10,000 people*).
- Immediate allergic reaction with symptoms such as skin rash, swelling or itching of the skin, red and swollen wyes, severe nasal congestion, asthma or wheezing. The reaction can be minor to life-threatening.
- Yellowing of the skin and the whites of your eyes, which may be a sign of jaundice (*very rare - may affect up to 1 in 10,000 people*) or inflammation of the liver (*uncommon - may affect up to 1 in 100 people*). Other symptoms may include loss of appetite, fever, general feeling of being unwell, nausea, dark urine and abdominal discomfort.
- A serious condition which causes the small vessels (capillaries) to leak (Capillary Leak Syndrome / Retinoic Acid Syndrome). This can lead to severe hypotension (low blood pressure), oedema (build up of fluid leading to swelling) and shock (collapse). Symptoms include swelling or puffiness, difficulty breathing, stomach cramps, muscle pain, excessive thirst, and a general feeling of tiredness and weakness (*side effect with unknown frequency*).
- A serious skin reaction with symptoms such as rash, blistering or peeling of the skin (Exfoliative dermatitis).

**Other side effects may include:**
**Stop taking Neotigason and see a doctor immediately if you get:**
* symptoms of an allergic reaction such as wheezing or difficulty in breathing, swelling of the face, tongue, lips or throat, itching, rash.

**Very common (affects more than 1 user in 10):**
* dry, irritated or swollen eyes, which may lead to intolerance of contact lenses;
* dry, irritated or runny nose, nose bleeding;
* dry mouth, thirst;
* dryness or inflammation of the lips, which may be alleviated by application of a fatty ointment. Itching, hair loss, peeling of the skin from the palms of hands or the soles of the feet or even rest of the body;
* thinning of the skin;
* changes in how the liver is working (shown by blood test);
* increased levels of fats in your blood (shown by blood test).

**Common (affects 1 to 10 users in 100):**
* headache;
* inflammation of the mucous tissue of the mouth, abdominal pain, diarrhoea, feeling sick, being sick;
* fragile skin, sticky feeling on the skin or a rash, skin inflammation, changes to the texture of the hair, brittle nails, skin infection around a nail, redness of the skin;
* joint pain, muscle pain;
* swelling of hands, ankles and feet.

**Uncommon (affects 1 to 10 users in 1,000):**
* dizziness;
* blurred vision;
* inflammation of the gums;
* fissures, cracks or fine linear scars in the skin e.g. around the mouth (rhagades), blisters and inflammation of the skin (dermatitis bullous), skin being more sensitive to the sun (photosensitivity reaction).

**Rare (affects 1 to 10 users in 10,000):**
* damage to the peripheral nervous system, which may include symptoms like muscle weakness, numbness and tingling in the feet and hands or burning, stabbing or shooting pain.

**Very rare (affects less than 1 user in 10,000):**
* night blindness, inflammation of the cornea in the eye (ulcerative keratitis);
* bone pain, changes in bone growth.

**Side effects with unknown frequency:**
* infection of the vagina (also known as candida or thrush);
* impaired hearing, ringing in the ear (tinnitus);
* flushing;
* impaired voice, ability to talk. Voice hoarse or weak.
* changes in the way things taste; bleeding in the rectum;
* small, reddish bumps on the skin that may bleed easily (pyogenic granuloma), loss of eyebrows (madarosis), swelling of the skin, skin rashes (causing itchiness or redness);
* improved or worsen glucose tolerance in diabetic patients;
* mood changes including irritability, aggression and depression.

An initial worsening of psoriasis symptoms is sometimes seen at the beginning of the treatment period.

**Reporting of side effects**
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: +353 1 6764971; Fax: +353 1 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.

## 5 How to store Neotigason

Keep this medicine out of the sight and reach of children.
Store in the original container, to protect from moisture. Do not store above 25°C.
Do not use this medicine after the expiry date which is stated on the the pack after EXP. The expiry date refers to the last day of the month.
Do not use this medicine if you notice any signs of deterioration.
Due to the risk of harmful effects on foetus, the medicine must not be passed on to other people. Unused or expired products must be returned to a pharmacy for disposal.

## 6 Contents of the pack and other information

**What Neotigason contains**
The active substance is acitretin. Each capsule contains 25 mg acitretin.
- The other ingredients are
**Capsule content:** gelatin, glucose liquid, spray-dried, sodium ascorbate and cellulose microcrystalline. **Capsule shell**: iron oxide black (E172), iron oxide yellow (E172), iron oxide red (E172), titanium dioxide (E171) and gelatin.
**Printing ink:** shellac, isopropyl alcohol, n-butyl alcohol, propylene glycol, ammonium hydroxide and iron oxide black (E172).

**What Neotigason looks like and contents of the pack**
Capsule with a brown cap and yellow body with 'Actavis' printed in black on the cap and '25' printed in black on the body; capsule size 1.
The capsules are supplied in blister packs of 60 capsules

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

**The manufacturer is:**
CENEXI SAS, 52 rue Marcel et Jacques Gaucher 94120 Fontenay-sous-Bois, France.

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