

Package leaflet: Information for the user

Neotigason® 10 mg capsules

acitretin

WARNING

CAN SERIOUSLY HARM AN UNBORN BABY

Women must use effective contraception

Do not use if you are pregnant or think you may be pregnant

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects

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:

- What Neotigason is and what it is used for
- What you need to know before you take Neotigason
- How to take Neotigason
- Possible side effects
- How to store Neotigason
- Contents of the pack and other information

1. What Neotigason is and what is it 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 or breast-feeding
- there is any chance you could become pregnant, you must follow the precautions under "Pregnancy and prevention programme", see section on "Warnings and precautions"
- 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;
- 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

Talk to your doctor before taking Neotigason:

- If you have ever had any mental health problems including depression, aggressive tendencies or mood changes. This is because taking Neotigason may affect your mood.
- 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;

Pregnancy prevention programme

Women who are pregnant must not take Neotigason

This medicine 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). It also makes a miscarriage more likely. This may happen even if Neotigason is taken only for a short time during pregnancy.

- You must not take Neotigason if you are pregnant or if you think you might be pregnant.
- You must not take Neotigason if you are breastfeeding. The medicine is likely to pass into your milk and may harm your baby.
- You must not take Neotigason if you could get pregnant during treatment.
- You must not get pregnant for 3 years after stopping this treatment because some medicine may still be left in your body.

Women who could get pregnant are prescribed Neotigason under strict rules. This is because of the risk of serious harm to the unborn baby

These are the rules:

- Your doctor must explain the risk of harm to the unborn baby - you must understand why you must not get pregnant and what you need to do to prevent getting pregnant.
- You must have talked about contraception (birth control) with your doctor. The doctor will give you information on how not to get pregnant. The doctor may send you to a specialist for contraception advice.
- Before you start treatment, your doctor will ask you to take a pregnancy test. The test must show that you are not pregnant when starting treatment with Neotigason.

Women must use effective contraception before, during and after taking Neotigason

- You must agree to use at least one very reliable method of contraception (for example an intra uterine device or contraceptive implant) or, two effective methods that work in different ways (for example a hormonal contraceptive pill and a condom). Discuss with your doctor which methods would be suitable for you.
- You must use contraception for a month before taking Neotigason, during treatment and for 3 years afterwards.
- You must use contraception even if you do not have periods or you are not sexually active (unless your doctor decides this is not necessary).

Women must agree to pregnancy testing before, during and after taking Neotigason

- You must agree to regular follow-up visits, ideally every month.
- You must agree to have regular pregnancy tests, ideally every month during treatment and, because some medicine may still be left in your body, every 1 to 3 months for 3

years after stopping Neotigason (unless your doctor decides this is not necessary in your case).

- You must agree to extra pregnancy tests if your doctor asks you.
- You must not get pregnant during treatment or for 3 years afterwards because some medicine may still be left in your body.
- Your doctor will discuss all these points with you, using a checklist and will ask you (or a parent/guardian) to sign it. This form confirms that you have been told about the risks and that you will follow the rules above.

If you get pregnant while taking Neotigason, **stop taking the medicine straight away**, and contact your doctor. Your doctor may send you to a specialist for advice.

Also if you become pregnant within 3 years after you stop taking Neotigason, you should contact your doctor. Your doctor may send you to a specialist for advice.

Advice for men

The levels of oral retinoid in the semen of men taking Neotigason are too low to harm their partners' unborn baby. However, you must never share your medication with anyone.

Additional precautions

You should never give this medicinal product to another person. Please take any unused capsules to your pharmacist at the end of treatment.

You should not donate blood during treatment with this medicine and for 3 years after stopping Neotigason because an unborn baby could be harmed if a pregnant patient receives your blood.

Mental health problems

You may not notice some changes in your mood and behaviour and so it is very important that you tell your friends and family that this medicine could affect your mood and behaviour. They may notice these changes and help you identify any problems that you need to talk to your doctor about.

Advice for all patients

Acitretin commonly increase blood fats, such as cholesterol or triglycerides which have been associated with pancreatitis.

Tell your doctor if you experience severe pain in the abdomen and back (these can be signs of inflammation of the pancreas).

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.
- 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.

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

For more information on pregnancy and contraception, see section 2 "Pregnancy and prevention programme".

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.

Important information about some of the ingredients of Neotigason:

This medicine 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. This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. How to take Neotigason

Always take this medicine 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).

Most people take Neotigason for up to 3 months. However, your doctor may decide that you need to take it for longer. You must not take Neotigason for more than 6 months at a time.

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 eyes, 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, Website: www.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.
Do not store above 25 °C. Store in the original package in order to protect from moisture.
Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that 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 10 mg acitretin.
The other ingredients are
Capsule contents: glucose, sodium ascorbate, microcrystalline cellulose, gelatin
Capsule shell: gelatin, iron oxide black (E 172), iron oxide yellow (E 172), iron oxide red (E 172), titanium dioxide (E 171)
Printing ink: shellac, isopropyl alcohol, n-butyl alcohol, propylene glycol, ammonium hydroxide, iron oxide black (E 172).

What Neotigason looks like and contents of the pack

Neotigason 10 mg is a brown cap and white body capsules, with '10' printed in black on the body.
Neotigason 10 mg is available in blisters of 60 hard capsules.

Manufacturer

Cenexi, 17, Rue de Pontoise, 95520 Osny, France.

Product procured from within the EU, repackaged and distributed by the PPA Holder:
PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

PPA 465/480/2

Neotigason is a registered trademark of Actavis Group PTC ehf.

This leaflet was last revised in March 2022.

Detailed and updated information on this product is available by scanning the QR code included in the PL with a smartphone. The same information is also available on the following URL: www.teva.ie/Neotigason_acitretin/p/ and the HPRA website, www.hpra.ie

