

Neotigason 10mg and 25mg Capsules

Acitretin

WARNING

CAN SERIOUSLY HARM AN UNBORN BABY

Women must use effective contraception

Do not use if you are pregnant or you 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.

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
2. What you need to know before you take Neotigason
3. How to take Neotigason
4. Possible side effects
5. How to store Neotigason
6. Contents of the pack and other information

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 maybe 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).

2. What you need to know before you take Neotigason

Do not take Neotigason if you are allergic to:

- Acitretin or any of the other ingredients of Neotigason (listed in Section 7).
- Other 'retinoid' medicines. These include isotretinoin and tazarotene.

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

- You have liver or kidney problems.
- You have very high levels of fat in your blood (also known as 'hyperlipidaemia').
- You are taking an antibiotic called tetracycline (for an infection) or a medicine called methotrexate (for skin problems, arthritis or cancer). See the section on 'Taking other medicines'.
- You are taking other retinoid medicines or medicines, vitamin supplements or foods that contain Vitamin A. See the section on 'Taking other medicines'.

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Neotigason if:

- You have diabetes. You will need to check your blood sugar levels more often when you start taking Neotigason.
- You have high levels of fat in your blood, you are obese, drink a lot of alcohol or at risk of heart problems. Your doctor may need to do blood tests while you are taking Neotigason to check the amount of fat and/or sugar in your blood and check your blood pressure.
- You are going out in strong sunlight or you are going to use a sun bed. Neotigason can make the effects of UV light on the skin stronger. Before going out into strong sunlight apply a sunblock to exposed skin.
- You have ever had any mental health problems including depression, aggressive tendencies or mood changes. This is because taking Neotigason may affect your mood.

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).

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.

A serious condition 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).

A serious skin reaction with symptoms such as rash, blistering or peeling of the skin (Exfoliative dermatitis) has been reported very rarely.

Neotigason may affect your liver function. Your doctor may need to do blood tests whilst you are taking this medicine to check your liver function.

Neotigason may cause increased pressure in the head. You should tell your doctor if you experience severe headaches, feeling or being sick or changes in sight. Your doctor may carry out further checks.

Neotigason may cause changes in bone growth. You should tell your doctor if you feel pain in your muscles or bones. Your doctor may carry out further checks.

High doses of Neotigason can cause mood changes such as irritability, aggression, depression.

Hair loss is a very common side effect of Neotigason.

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

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.

Children

Neotigason should not be given to children. Neotigason may cause changes in bone growth in children.

Other medicines and Neotigason

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Neotigason can affect the way some other medicines work. Also some other medicines can affect the way Neotigason works.

Talk to your doctor or pharmacist, if you are taking any of the following:

- An antibiotic called tetracycline (for an infection).
- A medicine called methotrexate (for skin problems, arthritis or cancer).
- Other retinoid medicines, such as isotretinoin or tazarotene.
- Medicines or vitamin supplements that contain Vitamin A.

Tell your doctor or pharmacist if you are taking the following medicine:

- Phenytoin (used to treat epilepsy).
- Low dose progesterone only contraceptives ('minipills').

Neotigason with food and 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 Neotigason and alcohol may result in formation of a compound (etretinate), which may be harmful to an unborn child, and if formed takes some time for it to be totally removed 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, which is a type of sugar. If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before taking this medicine. This medicine contains less than 1 mmol sodium (23mg) per tablet, that is to say essentially 'sodium-free'

3. How to take Neotigason

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- Take Neotigason at a meal time or with a drink of milk.
- Swallow each capsule whole.

The dose varies from one patient to another. Your doctor will work out the right dose for you.

Adults and elderly people

- The usual starting dose for adults and elderly people is 25mg or 30mg once a day.
- After 2 to 4 weeks, your doctor may increase or decrease your dose. This will depend on how well it works and how it affects you.
- The maximum dose is 75mg a day.
- 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 and adolescents

Neotigason should not be given to children. If it is given to a child, the doctor will decide the correct dose. This is based on the child's weight.

If you take more Neotigason than you should

If you take more Neotigason than you should, talk to a doctor or go to a hospital straight away.

Take the medicine pack with you. The following effects may happen: a bad headache, dizziness, feeling or being sick, being sleepy or irritable or having itchy skin.

If you forget to take Neotigason

- If you forget to take a dose, take it 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 (two doses at the same time) to make up for a forgotten dose.

If someone else takes your Neotigason capsules by mistake, they should talk to a doctor or go to a hospital straight away.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone will get them.

You will probably have some side effects during treatment with Neotigason, even before you see your skin starting to get better. These effects often wear off as your treatment continues. Your doctor can help you to deal with them.

Stop taking Neotigason and see a doctor straight away if you experience the following side effects:

- Immediate allergic reaction with symptoms such as skin rash, swelling or itching of the skin, swelling of the face, lips, throat or tongue, red and swollen eyes, severe nasal congestion, asthma or wheezing. The reaction can be minor to life-threatening.
- A severe headache.
- Feeling or being sick.
- Problems with your eye sight.
- You feel any aches and pains in your muscles, bones or joints. This may mean you have extra growth on the surface of your bones. This can happen if you take Neotigason for a long time.

Your doctor may want to check you regularly to find out if this is happening. These checks are particularly important if a child is taking Neotigason.

Other possible side effects:

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
- 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
- inflammation of the liver
- 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):

- increased blood pressure in the skull
- night blindness, inflammation of the cornea in the eye (ulcerative keratitis)
- yellowing of the skin or the whites of the eyes (jaundice)
- 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)
- a serious condition which causes the small blood 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).
- flushing; sweating, skin redness on the face
- changes in the way things taste; bleeding in the rectum
- a serious skin reaction with symptoms such as rash, blistering or peeling of the skin (Exfoliative dermatitis)
- small, reddish bumps or nodules on the skin that may bleed easily (pyogenic granuloma), scaling or thinning of the skin
- cracks or scarring at the corners of the mouth
- loss of eyelashes or eyebrows (madarosis)
- improved or worsened glucose tolerance in diabetic patients
- general unwell feeling, drowsiness
- swelling of the face, lips, throat or tongue (angioedema)
- severe itchy skin rash with pale or red irregular raised patches (hives)
- changes in the sound of the voice (dysphonia)

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 the Yellow Card Scheme website at

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Neotigason

- Keep Neotigason capsules in their original packaging to protect them from moisture.
- Do not store Neotigason capsules above 25°C.
- Keep this medicine out of the sight and reach of children.
- Do not use Neotigason capsules after the expiry date that is stated on the carton after "EXP". The expiry date refers to the last day of that month.
- Do not throw away any medicine via wastewater or household waste. Instead, return them to your pharmacist so that they can be disposed of carefully. Only keep them if your doctor tells you to. These measures will help protect the environment.

6. Contents of the pack and other information

What Neotigason contains

The active substance in Neotigason capsules is acitretin. There are two different strengths of capsules: Neotigason 10mg Capsules (each capsule contains 10mg acitretin) and Neotigason 25mg Capsules (each capsule contains 25mg acitretin). The other ingredients (in both strengths of capsule) are glucose (liquid, spray dried), sodium ascorbate, gelatine, purified water, microcrystalline cellulose, iron, oxide black (E172), iron oxide yellow (E172), iron oxide red (E172) and titanium dioxide (E171), shellac, n-butyl alcohol, isopropyl alcohol, propylene glycol and ammonium hydroxide.

What Neotigason looks like and contents of the pack

Neotigason 10mg capsules are brown and white, marked '10' on the white half. Neotigason 25mg capsules are brown and yellow, marked '25' on the yellow half.

The capsules are supplied in blister packs of 56 or 60 capsules or brown glass bottles with metal screw caps containing 30 or 100 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

Manufacturers

Cenexi, 52, rue Marcel et Jacques Gaucher, 94120 Fontenay – sous-Bois, France

Cenexi, 17, rue de Pontoise, 95520 Osny, France

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: <http://products.tevauk.com/p/acitretin-610> and www.mhra.gov.uk.



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