actavis

Neotigason 10mg and 25mg Capsules

Acitretin

Please read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them even if their symptoms are the same as yours.
- If any of the side effects become serious or troublesome, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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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).

2. Before you take Neotigason

Do not take Neotigason if you are allergic (hypersensitive) to:

- Acitretin or any of the other ingredients of Neotigason (listed in Section 7: Further information).
- 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 think you **may be pregnant** or you are **breast-feeding** (see Section 3: Important information for women).
- You **might get pregnant while taking Neotigason or within 2 years of stopping it** (see Section 3: Important information for women).
- 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 high levels of 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.

Take special care with Neotigason
Check with 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 or you are obese or drink a lot of alcohol. Your doctor may need to do blood tests while you are taking Neotigason to check the amount of fat in your blood.
- You are going out into 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.

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

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken 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.

Do not take Neotigason, and tell your doctor or pharmacist, if you are taking any of the following medicines:

- 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 high levels of Vitamin A (more than 5000 IU per day).
- Low dose progesterone only contraceptives ('minipills').

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

- Phenytoin (used to treat epilepsy).

Taking Neotigason with food and drink
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.

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 for blood donors
You must not give blood while you are taking Neotigason or for 2 years after you stop taking it.

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.

3. Important information for women

Neotigason will damage an unborn baby. The following **instructions must be strictly followed,** even if you have fertility problems:

Pregnancy and breast-feeding
Do not take Neotigason if:

- You are pregnant or think you may be pregnant or you are breast-feeding.
- You might get pregnant while taking this medicine or within 2 years of stopping it.

Birth control (contraception) and pregnancy tests
If you are a female patient at an age where you could get pregnant:

- **You must use an effective method of birth control** (contraception) for at least 1 month before you start taking Neotigason, while you are taking it, and for 2 years after you stop taking it.
- Your doctor will want you to **have a pregnancy test** about 2 weeks before starting treatment, which must be negative. You may also be asked to have regular pregnancy tests while you are taking Neotigason.
- Start taking Neotigason **after the negative pregnancy test**, on the second or third day of your next period.
- While you are taking Neotigason, and for 2 years after stopping it, **contact your doctor straight away if you get pregnant or think you may be pregnant.**

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

4. How to take Neotigason

Always take Neotigason exactly as your doctor has told you. You should 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.

Children

Neotigason is not normally 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 tablets 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.

5. Possible side effects

Like all medicines, Neotigason 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 get the following side effects at the same time:

- A severe headache.
- Feeling or being sick.
- Problems with your eye sight.

See a doctor straight away if:

- 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)
- flushing; sweating, skin redness on the face
- changes in the way things taste; bleeding in the rectum
- small, reddish bumps or nodules on the skin that may bleed easily (pyogenic granuloma), scaling or thinning of the skin
- cracks or scaring at the corners of the mouth
- improve or worsen glucose tolerance in diabetic patients.
- general unwell feeling, drowsiness

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

If any of the side effects become serious or troublesome, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

6. 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 out of the reach and sight of children.
- Do not use Neotigason capsules after the expiry date printed on the pack.
- Do not throw away any left over capsules. Instead, return them to your pharmacist so that they can be disposed of carefully. Only keep them if your doctor tells you to.

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

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