

Please read this leaflet carefully before you start to take your medicine. If you have any questions or are not sure about anything, ask your dermatologist or alternatively your doctor or pharmacist.

What is Neotigason?

Neotigason contains the active ingredient acitretin. Two strengths are available:

- the capsules with a brown cap and white body contain 10mg acitretin
- the capsules with a brown cap and yellow body contain 25mg acitretin
- both capsules contain the inactive ingredients maltodextrin, sodium ascorbate, gelatin, purified water, microcrystalline cellulose, iron oxide black (E172), iron oxide yellow (E172), iron oxide red (E172) and titanium dioxide (E171).

Acitretin is one of a group of medicines known as retinoids which are normally used to treat skin problems.

- Both capsule strengths come in blister packs of 56

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What is Neotigason used for?

This medicine is used to treat skin problems characterised by the thickening and shedding of the skin, such as psoriasis. The use of Neotigason must be supervised by a dermatologist (a doctor who specialises in the treatment of skin problems).

To help you get the full benefits from this medicine you should read this leaflet carefully and ask your dermatologist to explain anything you do not understand.

When must Neotigason not be used?

- If you are pregnant or think you may be pregnant
- If you have liver or kidney disease
- If you are breast-feeding
- If you are taking certain antibiotics called tetracyclines
- If you have very high fat levels in your blood
- If you are taking other preparations containing high levels of Vitamin A
- In children, unless the doctor considers it necessary.
- If you are allergic to Neotigason or any of the ingredients it contains.

Make sure your doctor knows if you are taking methotrexate (another drug used to treat skin problems).

When should you be extra careful when using Neotigason?

Make sure your doctor knows if:

- You, or members of your family, have a history of high triglyceride (a fat-like substance) levels in the blood
- You, or members of your family have diabetes mellitus (sugar diabetes)
- You drink a lot of alcohol

This is because acitretin may increase blood levels of fat-like substances in these patients. Because of this, you **should not** drink alcoholic drinks or at least reduce the amount you usually drink while taking Neotigason. If your doctor finds that you have got high levels of triglycerides while taking this medicine, you may need to go on a low-fat diet.

- Do not take more than the recommended daily dietary allowance of vitamin A a day (ie 4000 to 5000 International Units). If you take vitamins check the label to see how much vitamin A they contain. If you are not sure, ask your doctor or pharmacist.
- Make sure your doctor knows if you are taking phenytoin (a drug used to treat epilepsy).
- You may become more sensitive to sunlight while taking this medicine. Avoid too much sun and do not use a sunlamp. Before going out into strong sunlight apply a sunblock to exposed skin.

● *Special note for blood donors*

You should not donate blood either during or for at least one year after Neotigason treatment.

Neotigason **MUST NOT** be taken during pregnancy

IMPORTANT

Neotigason will damage an unborn baby.

Female patients must strictly follow these instructions

- You must not take Neotigason if you are pregnant or think you may be pregnant.
- You must use an effective method of birth control for one month before treatment, during treatment and for **two years** after treatment ends. Before you start treatment, your doctor should ask you to take a pregnancy test, which must be negative. You should start taking Neotigason on the second or third day of your menstrual cycle.
- You must not become pregnant at any time during treatment or for two years after treatment ends.
- Contact your dermatologist immediately if you do become pregnant or think you may be pregnant during treatment or in the two years after treatment ends.

How should Neotigason be taken?

- Always take the capsules as your doctor tells you to.
- Your doctor will tell you how much medicine to take. The usual starting dose is 25mg or 30mg a day, although lower starting doses are sometimes required. After 2 to 4 weeks your doctor may change the dose. This will depend on how you are getting on with your medicine.
- You will usually be on a dose of between 25mg and 50mg a day for another 6 to 8 weeks. However, higher doses or longer treatment times up to 6 months are sometimes needed. Normally, you should not take more than 75mg per day. For children, the maximum dose is 35mg per day.
- The capsules should be taken at mealtimes with a drink of water. Swallow the capsules whole, do not suck or chew them.
- If you are a woman of child bearing age you should have been using an effective method of contraception for at least 1 month prior to starting Neotigason. You should start taking Neotigason on the second or third day of your menstrual cycle.
- If you miss a dose, take it as soon as possible. However, if it is nearly time for your next dose, skip the missed dose and carry on as before. Do not take a double dose.
- When your skin has improved, your doctor will probably stop giving you Neotigason. You should remember though that your condition can flare up again so you may need more treatment courses.
- If you take too many capsules or someone else accidentally takes your medicine, contact your doctor, pharmacist or the nearest hospital straight away.

What are the possible unwanted effects of Neotigason?

You will probably have some unwanted reactions to your treatment, even before you see your skin getting better. These effects often wear off as your treatment continues and your doctor can help you to deal with them.

- **Dryness:** You should expect dryness of the skin, especially of the lips and face and you may get some mild itching and slight peeling. Your skin may become redder than usual. This dryness can be relieved by the regular use of good moisturising cream from the start of treatment. Petroleum jelly is particularly good. The inside of the nose may become inflamed, dry and 'crusted' causing mild nose bleeds. Smearing a thin layer of petroleum jelly on the inside of the nose will help.
- **Eye irritation:** Your eyes may feel dry and slightly irritated which may lead to conjunctivitis. This may be a problem if you wear contact lenses. Ask your pharmacist to suggest some suitable eye drops to help.
- **Hair loss:** You may notice some changes in your hair texture or hair loss after taking the medicine for a while. This is only temporary. Your hair should return to normal after the treatment ends.

- **Muscle aches and pains:** Some people have muscle aches and pains when they are taking this medicine. These will normally be relieved by avoiding vigorous exercise. However, if you get severe muscle aches or joint pains call your doctor straight away.
- **Skin peeling:** You may notice that skin which was not affected before - on the hands and feet, for example - may start to peel. This will heal completely after treatment ends. Your skin may also blister more easily during therapy.
- Other less common unwanted effects include headaches, tiredness, nausea, sweating, swelling of arms and legs, poor night vision, blurred vision, gum disease, nail fragility, infections round the base of the nail, thrush, jaundice and liver disease. Most of the unwanted effects of Neotigason will disappear when you stop treatment.
- If your sight is affected by this medicine tell your doctor straight away and do not drive or operate machinery.
- If you are worried about these or any other unwanted effects, talk to your doctor.

How should Neotigason be stored?

- The capsules should be stored in the original package. Do not store above 25°C.
- Keep this medicine out of the reach and sight of children.
- This medicine must not be used after the date (EXP) printed on the pack. Return any left over medicine to your pharmacist. Only keep it if your doctor tells you to.
- REMEMBER this medicine is for you. Only a doctor can prescribe it for you. Never give it to others. It may harm them even if their symptoms are the same as yours.

Further information:

You can get more information on Neotigason from your doctor or pharmacist.

Date of last review

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