

NEOTIGASON CAPSULES

Acitretin (10mg, 25mg)

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What Neotigason is used for

Neotigason is used to treat:

- extensive and serious forms of psoriasis.
- severe dry scales as a result of marked keratinization such as ichthyosis (a group of skin disorders characterized by dry, scaly, or thickened skin), pityriasis (a temporary rash of raised red scaly patches on the body) or Darier's disease (a skin condition characterized by wart-like blemishes on the body).

How Neotigason works

Acitretin belongs to a group of medicines known as retinoids. Retinoids are derived from vitamin A.

The way acitretin works is not known.

Before you use Neotigason

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.

-When you must not take it

Do not take Neotigason if:-

- you are pregnant or breast-feeding
- there is any chance you could become pregnant.

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 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.

If you get pregnant while taking Neotigason, stop taking the medicine straight away, and contact your doctor.

Also, if you become pregnant within 3 years after you stop taking Neotigason, you should contact your doctor.

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, especially females.

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.

Do not take Neotigason also if:

- you have severe liver problems
- your kidneys are not working properly.
- you have very high levels of fat or cholesterol in your blood (also known as "hyperlipidaemia").
- you are taking some medications (see "Taking other medications").

- you are allergic (hypersensitive) to acitretin or any of the other ingredients of this medicine. Hypersensitivity usually shows itself in the form of skin reactions, such as a rash, hives and/or itching.

If one or more of these warnings are applicable for you, talk to your doctor before taking Neotigason.

-Before you start to take it

Talk to your doctor or pharmacist before you take Neotigason if:

- you have liver problems. You will need to check that your liver is functioning normally before starting Neotigason.
- you have high levels of cholesterol and triglycerides in your blood.
- you suffer from high levels of sugar in the blood (diabetes). You will need to check your blood sugar levels more often when you start taking this medicine.
- you have a condition called ossification, an abnormal bone formation.
- you drink alcohol (see "Acitretin with food and alcohol"). Talk to your doctor about your alcohol use.
- Neotigason is to be used in children. Growth and bone development must be checked at regular intervals. In long-term

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treatment of children, the doctor must carefully weigh the possible severe side effects against the benefit of therapy with this medicine.

- you have visual problems. Taking Neotigason can decrease night vision and needs to be monitored.
- you are woman taking contraceptive pills (mini-pills)
- you have ever had any kind of mental health problems. This includes depression, aggressive tendencies or mood changes.

-Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. The effect of phenytoin (a medicine for epilepsy) may be increased by Acitretin. The dosage of phenytoin may need to be reduced.

Do not take Acitretin together with:

- the antibiotic tetracycline
- methotrexate (a medicine that is used in the treatment of cancer, psoriasis and rheumatic diseases)
- the mini-pill (a contraceptive pill with only a low progesterone content). Acitretin may reduce the contraceptive effect, therefore you must not use these pills as a contraceptive together with Neotigason.
- vitamin A supplements and other retinoid medicines.

Acitretin with food and alcohol

You should not drink alcohol during treatment with Neotigason as the risk for side effects would be increased.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy

You must NOT take Neotigason if you are pregnant. If you do get pregnant during treatment with this medicine in spite of the described precautions or in the 3 years following treatment, there

is a high risk of severe malformations of the unborn baby. Therefore you should NEVER use Neotigason during pregnancy and you should not get pregnant within 3 years following treatment. (see "**Before you use Neotigason**")

Breast-feeding

You must not take Neotigason if you are breastfeeding, because acitretin passes into the milk and may harm the baby.

Driving and using machines

Your night vision may get worse during treatment. This can happen suddenly. Be careful if you are driving or using any tools or machines at night.

How to take Neotigason

-How much to take

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, preferably with a drink of milk.

- Swallow each capsule whole.

The dose varies from one person 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 25 mg or 30 mg 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 75 mg a day.

- The maintenance therapy for keratinization is usually needed, though the lowest possible dosage should be given. This may be less than 20 mg/day and should not exceed 50 mg/day.

Use in children and adolescents

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.

The daily dosage is about 0.5 mg/kg. Higher doses (up to 1

mg/kg daily) may be necessary in some cases for limited periods, but only up to a maximum of 35 mg/day.

The maintenance dose should be kept as low as possible in view of possible long-term side effects.

Combination treatment

When Neotigason is used in combination with other types of therapy, it may be possible to reduce the dosage of Neotigason, depending on the person's individual response. Standard topical treatments can generally be continued and do not interfere with Neotigason.

-When to take it

Take Neotigason exactly as prescribed. Your doctor will tell you when to take. It is advised to take Neotigason at the same time each day.

-How long to take it

Always take this medicine exactly as your doctor has told you.

In adults receiving long-term treatment with Neotigason, appropriate examinations should be periodically performed.

-If you forget to take it

Do not take a double dose of Neotigason to make up for a forgotten dose. If you forget to take a dose, take it as soon as you remember and continue according to the dosing schedule.

However, if it is nearly time for the next dose, skip the missed dose.

-If you take too much (overdose)

If you take more Neotigason than you should, you may suffer from headache, nausea and/or vomiting, drowsiness, irritability and itching.

Stop taking the medicine and consult your doctor immediately.

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While you are using Neotigason

-Things you must do

You must follow the precautions for the treatment with Neotigason.

You should never give this medicinal product to another person.

Ethanol should be avoided for 2 months after cessation of Neotigason therapy.

-Things you must not do

Do not drive a car, work with machines, or do other dangerous activities until you know how Neotigason affects you.

Do not donate blood during and for 3 years after completion of treatment with Neotigason.

-Things to be careful of

Neotigason is highly teratogenic. Its use is contraindicated not only in pregnant women and women who might become pregnant during or within 3 years of the cessation of treatment, but in all women of childbearing potential.

Side Effects

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

The side effects of acitretin are dose related. The higher the daily dose, the greater the risk of side effects.

Most side effects occur at the start of treatment when the dose still has to be adjusted. Most side effects are reversible after altering the dose or discontinuation of treatment.

Occasionally the symptoms of your skin may get worse in the beginning of treatment.

As Acitretin is a vitamin A derivative, most of its side effects are similar to the symptoms that occur if someone has used too much vitamin A.

Below are some side effects that may occur:

- dry skin and mucous membranes of the nose, dry lips and possibly inflamed lips.

- inflammation of the nasal mucosa.

- scaling and thinning of healthy skin especially on the palms and soles

- reddening of the skin

- itching

- “sticky skin” sensation

- hair loss

- fragile nails

- feeling more thirsty than usual
- visual disturbances such as dry eye, blurred vision, impaired night vision. Wearing of contact lenses might become impossible.

- severe headache, nausea, vomiting, and visual disturbances. If you experience any of these symptoms, please discontinue Neotigason immediately and see your doctor.

- muscle, joint and bone pain. After long-term treatment with Neotigason, bone changes may occur (spinal problems) and calcifications in soft tissues (ligaments and tendons).

- increased retention of water in the body (oedema)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Neotigason

-Storage

Do not store above 25°C, store in the original package.

-Disposal

Do not use after the expiry date stated on the label.

Take any unused capsules back to your pharmacist to be destroyed. Only keep the capsules if the doctor tells you to. Do not throw them away with your normal household water or waste. This will help to protect the environment.

Product Description

-What it looks like

The 10 mg capsules have a brown cap and a white body with 10 printed in black on both cap and body.

The 25 mg capsules have a brown cap and a yellow body with 25 printed in black on both cap and body.

Capsule content: powder, eventually with lumps, yellowish to yellow.

-Ingredients

Active Ingredient

Acitretin.

Capsules 10 mg and 25 mg.

Inactive ingredients

Glucose, microcrystalline cellulose, sodium ascorbate.

Hard capsules

10mg

Body: titanium dioxide, gelatin

Cap: iron oxide black iron oxide yellow iron oxide red, titanium dioxide, gelatin

25mg

Body: Titanium dioxide, gelatin, iron oxide yellow

Cap: iron oxide black, iron oxide yellow, iron oxide red, titanium dioxide, gelatin

-MAL number

Neotigason capsules 10mg: MAL06091392ACZ

Neotigason capsules 25mg: MAL06091393ACZ

Manufacturer

Made under licence from

Actavis Group PTC ehf.

Dalshraun 1, 220 Hafnarfjörður, Iceland.

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

Product Registration Holder

DCH Auriga (Malaysia) Sdn. Bhd.

Lot 6, Persiaran Perusahaan Seksyen 23, 40300 Shah Alam Selangor, Malaysia

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