

NEOTIGASON®

Acitretin

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about NEOTIGASON capsules.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking NEOTIGASON Capsules against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What is Neotigason used for

NEOTIGASON contains the active ingredient acitretin.

NEOTIGASON is used to treat severe psoriasis (skin disease with thickened patches of red skin, often with silvery scales) and other severe disorders of the skin.

NEOTIGASON belongs to a group of medicines called retinoids, which are very similar to Vitamin A. Vitamin A, which we obtain from food, is important for the normal growth and development of the body, especially the skin.

In severe psoriasis and some other skin disorders, where there is problem with the normal development of the skin,

NEOTIGASON helps return the skin to normal.

There are many different types of medicines used to treat skin conditions.

Your doctor may have prescribed NEOTIGASON for another purpose.

Ask your doctor if you have any questions why NEOTIGASON has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you take Neotigason

Do not take NEOTIGASON if:

- **you are pregnant, or intend to become pregnant during treatment or in the 3 years after stopping treatment.**

The possibility that you may be pregnant must be ruled out by you and your doctor before you start taking Neotigason.

A pregnancy test must be negative when performed within one week before beginning of treatment.

NEOTIGASON is highly teratogenic and there is an extremely high risk that a severely deformed baby will result if taken before or during pregnancy, no matter for how long or at what dose.

You must use effective contraception (preferably two complementary forms), without interruption for one month before, during and 3 years after treatment.

A combination hormonal contraceptive product or an intrauterine device should be used. It is recommended that a diaphragm is also used. Low dose minipills (progesterone only) are not recommended.

- **you are breastfeeding. Breastfeeding must be stopped before treatment begins. Do not breastfeed while taking NEOTIGASON.**
- you have had an allergic reaction to NEOTIGASON, Vitamin A, other retinoids or any ingredients listed in the Ingredients section of this leaflet.
- you are taking tetracycline antibiotics (such as doxycycline HCl: In Australia, Doryx®, Vibramycin®; in New Zealand Doxine®, Doxy 50®, or Minocycline HCl, Minomycin®)
- you are taking vitamin A, or preparations containing vitamin A.
- You have severe liver or kidney disease or abnormally high fat levels in your blood
- You are also taking methotrexate

Do not take NEOTIGASON after the expiry date (EXP) printed on the pack.

It may have no effect or, worse, an entirely unexpected effect if you take it after the expiry date.

Do not take NEOTIGASON if the package is torn or shows signs of tampering.

If you are not sure if you should be taking NEOTIGASON, talk to your doctor.

You must tell your doctor if:

1. **you are allergic to any other medicines, foods, dyes or preservatives.**
2. **you have any other health problems including:**
 - diabetes, or a history of diabetes in your family
 - liver disease
 - high triglycerides or cholesterol levels in the blood, or a history of high blood triglycerides or cholesterol levels in your family

Taking other medicines

Tell your doctor if you are taking any other medicines including any that you have bought from a pharmacy, supermarket or healthfood shop.

Other medicines may interfere with NEOTIGASON. These medicines include:

- tetracycline antibiotics (such as minomycin, or in Australia, Vibramycin®; in New Zealand, Doxine®)
- phenytoin (such as Dilantin®)
- methotrexate
- alcohol containing medicines
- you are taking a low-dose progestogen oral contraceptive (also called the "mini-pill")
- vitamin A supplements, or preparations containing vitamin A.

Your doctor or pharmacist has a complete list of medicines to avoid while taking NEOTIGASON.

If you have not told your doctor about any of the above, tell them before you start taking NEOTIGASON.

Use NEOTIGASON exactly as your doctor has prescribed.

Use in Children

NEOTIGASON should only be used in children where alternative therapy cannot be used.

How to take Neotigason

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet

How much to take

Take NEOTIGASON exactly as your doctor has prescribed.

Your doctor will tell you how many NEOTIGASON Capsules to take each day.

This quantity will be especially matched to your needs and whether you develop any side effects.

The initial dose is usually 25 mg (1 x 25 mg capsule) or 30 mg (3 x 10 mg capsules) per day for 2 to 4 weeks. Your dose will probably then be adjusted.

You may notice the first signs of improvement during the first week but, more often, after 2 or 3 weeks. It may take 2 to 3 months before the full effect is seen.

The affected skin will either peel off or gradually clear. Sometimes there will be more redness or itching at first, but this will normally improve as treatment continues.

How to take it

Capsules should be swallowed whole with a glass of water or milk.

When to take it

NEOTIGASON is usually taken once daily with meals or with a glass of milk.

If you are female, you should wait until the 2nd or 3rd day of your next normal menstrual period before you start NEOTIGASON therapy.

How long to take NEOTIGASON

Continue taking NEOTIGASON until your doctor tells you to stop.

If you forget to take NEOTIGASON

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember and then go back to taking it as you would normally.

Do not double a dose to make up for one you have missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering your dose, ask your pharmacist for some hints.

In case of an overdose

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) in Australia or New Zealand National Poisons Centre (0800764766) for advice or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much NEOTIGASON. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

There is no information currently available on the effects of overdose with NEOTIGASON. However, based on experience with excessive vitamin A and other drugs similar to NEOTIGASON, signs of overdosage may include transient headache, vomiting, flushed face, dry skin and lips, pain in the stomach, dizziness and unco-ordination. You should recover without any after effects. You may need some tests to see if your liver has been affected.

Keep telephone numbers for these places handy.

If you are not sure what to do, contact your doctor or pharmacist.

While you are taking Neotigason

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking NEOTIGASON.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Your doctor may want to do some blood, liver function and other tests from time to time to check on your progress and detect any unwanted side effects.

Your cholesterol and serum triglyceride levels should be monitored when NEOTIGASON is used for a long time.

Tell your doctor if you are taking vitamin supplements that contain greater than 2500 IU of Vitamin A. If you are not sure, check with your doctor or pharmacist.

Avoid alcohol in drinks, food or medicines during treatment.

Alcohol should also be avoided for 2 months after stopping treatment with NEOTIGASON.

FOR FEMALE PATIENTS:

You must use two forms of birth control without interruption for at least 1 month before you start NEOTIGASON and for the whole time you are taking NEOTIGASON and for at least 3 years after you finish taking NEOTIGASON.

Therapy should be started on the second or third day of your next normal menstrual period.

Stop taking NEOTIGASON immediately and tell your doctor if you do become pregnant while you are taking NEOTIGASON. You must also tell your doctor if

you become pregnant in the three years following the end of treatment.

Your doctor may ask you to have a pregnancy test every month during use and every 1-3 months after stopping until 3 years have passed.

Things you must not do

Do not stop taking NEOTIGASON or lower the dose without first checking with your doctor.

Do not let yourself run out of medicine over the weekend or on holidays.

Do not donate blood during treatment or for at least 3 years after stopping treatment.

Do not use oral contraceptive "Minipills" (progestogen only pills) as contraception during treatment.

Do not give NEOTIGASON to anyone else even if their symptoms seem similar to yours.

Do not use NEOTIGASON to treat other complaints unless your doctor says to.

Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist.

Things to be careful of

Normally your ability to drive cars or operate machinery is not affected by NEOTIGASON, however decreased night vision has been reported. Patients may need to be cautious before they drive a car or operate machinery at night.

Wearing contact lenses during treatment and for a little while after treatment with NEOTIGASON may cause discomfort. An eye lubricant, or artificial tears, available from your pharmacist (chemist), will assist with this problem. Otherwise, you may temporarily need to wear glasses instead.

Your skin may be more sensitive to sunburn while on NEOTIGASON.

Avoid excessive sun exposure and apply a sunscreen while taking NEOTIGASON.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking NEOTIGASON.

NEOTIGASON helps most people with skin conditions but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

If side effects do occur, they may be:

- dryness of the lips, mouth, nose, eyes and skin. A moisturiser or petroleum jelly can be used to soften the lining of the nose, lips and the skin
- thinning or peeling of the skin that was not previously affected (for example, hands and feet)
- sticky skin may occur
- hair loss sometimes occurs (and in rare cases, has persisted)
- rash, "redness of the skin" or itchiness
- flushing.

These side effects will probably stop after the dose of NEOTIGASON is lowered or stopped.

Tell your doctor if you notice any of the following and they worry you:

- unusually severe or persistent headaches
- nausea
- diarrhoea
- tenderness or stiffness in your joints or muscles or bones

- fatigue
- dizziness
- sleepiness
- mood changes
- depression
- male breast enlargement
- water retention
- gastritis
- heartburn
- changes in hearing
- irregular menstrual bleeding
- sore mouth or inflammation of the gums
- taste disturbances
- tingling, numbing or weakness in the hands or feet.

These side effects could mean that the dose of NEOTIGASON needs to be adjusted.

Stop taking NEOTIGASON and see your doctor if you experience any of the following:

- nausea
- vomiting
- headache
- blurred vision or visual disturbances

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking Neotigason

Keep your capsules in the blister pack until it is time to take them.

If you take the capsules out of the blister pack they may not keep well.

Keep NEOTIGASON in a cool dry place where the temperature

stays below 25°C. Do not store it, or any other medicine, in a bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Protect NEOTIGASON from light.

Keep NEOTIGASON where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking NEOTIGASON, or the capsule has passed its expiry date, you should return any capsules remaining at the end of treatment to your dermatologist.

Product description

What NEOTIGASON looks like

NEOTIGASON 10 mg hard gelatin capsules have a white opaque body and a brown opaque cap with a "10" printed on the body.

NEOTIGASON 25 mg hard gelatin capsules have a yellow opaque body and a brown opaque cap with a "25" printed on the body.

Ingredients

Active ingredient - acitretin

- each 10 mg capsule contain 10 mg acitretin
- each 25 mg capsule contain 25 mg acitretin

Inactive ingredients -

- gelatin, glucose liquid spray-dried, sodium ascorbate, microcrystalline cellulose and the colours iron oxide black (CI77499), iron oxide yellow (CI 77492), iron oxide red (CI 77491) and titanium dioxide.

NEOTIGASON Capsules are gluten free.

NEOTIGASON Capsules are lactose free.

NEOTIGASON Capsules come in cartons of 100.

In Australia

Sponsor:

Teva Pharma Australia Pty Ltd
Level 1, 37 Epping Rd
Macquarie Park, NSW, 2113
Telephone: 1800 288 382

In New Zealand

Sponsor and Distributor:

Teva Pharma (New Zealand) Limited
Auckland, New Zealand

Please check with your pharmacist for the latest Consumer Medicine Information.

Australian Registration Numbers:

NEOTIGASON 10 mg has the registration number AUST R 52455

NEOTIGASON 25 mg has the registration number AUST R 52456.

This leaflet was updated in July 2018