

NEOTIGASON[®]

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using NEOTIGASON?

NEOTIGASON contains the active ingredient acitretin. NEOTIGASON belongs to a group of medicines called retinoids, which are very similar to Vitamin A. 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.

For more information, see Section [1. Why am I using NEOTIGASON?](#) in the full CMI.

2. What should I know before I use NEOTIGASON?

Do not use if you have ever had an allergic reaction to NEOTIGASON, retinoids or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions or take any other medicines. NEOTIGASON should not be used if you are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use NEOTIGASON?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with NEOTIGASON and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use NEOTIGASON?

- NEOTIGASON is usually taken once daily swallowed whole with meals or with a glass of milk

More instructions can be found in Section [4. How do I use NEOTIGASON?](#) in the full CMI.

5. What should I know while using NEOTIGASON?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using NEOTIGASON.• Your doctor may want to do some blood, liver function and other tests from time to time.• Your cholesterol and serum triglyceride levels should be monitored when NEOTIGASON is used for a long time.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking NEOTIGASON or lower the dose without first checking with your doctor.• Do not donate blood during treatment or for at least 3 years after stopping treatment.• Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist.
Driving or using machines	<ul style="list-style-type: none">• Decreased night vision has been reported. Patients may need to be cautious before they drive a car or operate machinery at night.
Drinking alcohol	<ul style="list-style-type: none">• Avoid alcohol in drinks, food or medicines during treatment.• Alcohol should also be avoided for 2 months after stopping treatment with NEOTIGASON.
Looking after your medicine	<ul style="list-style-type: none">• Store below 25°C• Store in original package to protect from moisture

For more information, see Section [5. What should I know while using NEOTIGASON?](#) in the full CMI.

6. Are there any side effects?

Common side effects can include dryness of the lips, mouth, nose, eyes and skin, thinning or peeling of the skin, thirst, flushing, rash, "redness of the skin" or itchiness.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

NEOTIGASON[®]

capsules

Active ingredient(s): acitretin

Consumer Medicine Information (CMI)

This leaflet provides important information about using NEOTIGASON. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using NEOTIGASON.**

Where to find information in this leaflet:

- [1. Why am I using NEOTIGASON?](#)
- [2. What should I know before I use NEOTIGASON?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use NEOTIGASON?](#)
- [5. What should I know while using NEOTIGASON?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using NEOTIGASON?

NEOTIGASON contains the active ingredient acitretin. 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.

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.

In severe psoriasis and some other skin disorders, where there is a 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.

2. What should I know before I use NEOTIGASON?

Warnings

Do not use NEOTIGASON if:

- you are allergic to acitretin, vitamin A, other retinoids or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- You are pregnant, or intend to become pregnancy during treatment or in the 3 years after stopping treatment.

- You are a woman of childbearing potential unless all of the conditions of the Pregnancy Prevention Programme are met.
- You are taking tetracycline antibiotics (such as doxycycline HCl or Minocycline HCl)
- You are taking vitamin A, or preparation containing vitamin A.
- You have severe liver or kidney disease or abnormally high fat levels in your blood.
- You are also taking methotrexate

Check with your doctor if you:

- have any other medical conditions 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
- take any medicines for any other condition
- are allergic to any other medicines, foods, dyes or preservatives

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

NEOTIGASON should not be taken 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 or condom is also used. Low dose minipills (progesterone only) are not recommended.

Breastfeeding must be stopped before treatment begins. Do not breastfeed while taking NEOTIGASON.

Children

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

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with NEOTIGASON and affect how it works. These medicines include:

- tetracycline antibiotics
- phenytoin
- methotrexate
- alcohol containing medicines
- 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect NEOTIGASON.

4. How do I use NEOTIGASON?

How much to take

- 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.
- Follow the instructions provided and use NEOTIGASON until your doctor tells you to stop.
- 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.

When to take NEOTIGASON

- NEOTIGASON is usually taken once daily swallowed whole 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.

If you forget to take NEOTIGASON

NEOTIGASON should be used regularly at the same time each day.

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 take a double dose to make up for the dose you missed.

If you use too much NEOTIGASON

If you think that you have used too much NEOTIGASON, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (In Australia by calling 13 11 26 and in New Zealand 0800 POISON [0800 764 766]), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

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 itchy skin and lips, pain in the stomach, drowsiness, dizziness and unco-ordination. You should recover without any after effects. You may need some tests to see if your liver has been affected.

5. What should I know while using NEOTIGASON?

Things you should do

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.

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.

Call your doctor straight away if you:

- become pregnant while you are taking NEOTIGASON. Stop taking NEOTIGASON immediately
- become pregnant in the three years following the end of treatment.

Remind any doctor, dentist or pharmacist you visit that you are using NEOTIGASON.

Things you should 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.

Eyes and Skin

- 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, 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how NEOTIGASON affects you.

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.

Drinking alcohol

Tell your doctor if you drink alcohol.

Avoid alcohol in drinks, food or medicines during treatment.

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

Looking after your medicine

- 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.
- Store below 25°C.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Skin and Hair related: <ul style="list-style-type: none">• 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)• nail fragility• sticky skin may occur• hair loss sometimes occurs (and in rare cases, has persisted)• rash, "redness of the skin" or itchiness• flushing	Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.
Blood test abnormalities: <ul style="list-style-type: none">• changes in how the liver is working (shown by blood test)• increased levels of fats in your blood (shown by blood test)	
Other: <ul style="list-style-type: none">• headache• nausea• diarrhoea• fatigue	

Less serious side effects	What to do
<ul style="list-style-type: none"> 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 thirst tingling, numbing or weakness in the hands or feet. eye irritation and intolerance to contact lenses eye infection 	

Serious side effects

Serious side effects	What to do
<p>Symptoms of immediate allergic reaction:</p> <ul style="list-style-type: none"> 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 <p>Other:</p> <ul style="list-style-type: none"> severe or persistent headache nausea or vomiting blurred vision or visual disturbances tenderness or stiffness in your joints or muscles or bones 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration OR Medsafe online at www.tga.gov.au/reporting-problems OR <https://nzphvc.otago.ac.nz/reporting/> By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What NEOTIGASON contains

Active ingredient (main ingredient)	acitretin
Other ingredients (inactive ingredients)	gelatin, glucose liquid spray-dried, sodium ascorbate, microcrystalline cellulose and the colours iron oxide black (CI 77499), iron oxide yellow (CI 77492), iron oxide red (CI 77491), titanium dioxide and OPACODE monogramming ink S-1-17822 and S-1-17823 BLACK

Do not take this medicine if you are allergic to any of these ingredients.

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 (AUST R 52455).

NEOTIGASON 25 mg hard gelatin capsules have a yellow opaque body and a brown opaque cap with a "25" printed on the body (AUST R 52456).

NEOTIGASON Capsules are gluten free.

NEOTIGASON Capsules are lactose free.

NEOTIGASON Capsules come in cartons of 10, 30, 100*.

*Not all pack sizes may be marketed

Who distributes NEOTIGASON

Teva Pharma Australia Pty Ltd

Level 1, 37 Epping Road

Macquarie Park NSW 2113

Ph: 1800 288 382

Teva Pharma (New Zealand) Ltd

Auckland, New Zealand

This leaflet was prepared in January 2025.