

NOVATRETIN™

Acitretin, 10 mg and 25 mg Capsules

What is in this leaflet

This leaflet answers some of the common questions about NOVATRETIN capsules.

It does not contain all the information that is known about NOVATRETIN.

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 taking NOVATRETIN against the benefits they expect it will have for you.

If you have any concerns about taking NOVATRETIN capsules, ask your doctor or pharmacist.

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

What are NOVATRETIN capsules used for

The active ingredient in NOVATRETIN capsules is acitretin, which belongs to a group of medicines called retinoids.

It is very similar to Vitamin A which is obtained from our diet and is vital for the normal growth and development of the body, especially the skin.

Psoriasis is a skin disease with thickened patches of red skin, often with silvery scales. NOVATRETIN is used to treat severe psoriasis and other severe skin disorders.

NOVATRETIN works to return skin to normal when problems with the normal development of the skin are present, as in the case of severe psoriasis and some other skin disorders.

There are various types of medicines used to treat skin conditions.

You may have been prescribed NOVATRETIN by your doctor for another reason.
If you have any questions about why NOVATRETIN has been prescribed for you, ask your doctor.

NOVATRETIN is only accessible with a doctor's prescription.

Before you use NOVATRETIN

Do not take NOVATRETIN capsules if:

- you are pregnant or you intend to become pregnant in the next 24 months. Any possibility that you may be pregnant must be ruled out by both yourself and your doctor before you start taking NOVATRETIN capsules. The result of a pregnancy test must be negative when performed within two weeks before beginning of NOVATRETIN treatment. NOVATRETIN is highly teratogenic i.e. there is an extremely high risk of having a baby that is severely deformed. This means you must use effective contraception for one month before, during and 2 years after treatment with NOVATRETIN.
- you are breastfeeding. Breastfeeding must stop before NOVATRETIN treatment can start. Do not breastfeed while taking NOVATRETIN capsules.

- you have had an allergic reaction to NOVATRETIN capsules, Vitamin A, other retinoids or any ingredients listed in the Ingredients section of this leaflet.
- you are taking tetracycline antibiotics. These include Doxine[®], Doxy[®], Achromycin[®] and Minomycin[®].
- you are taking vitamin A, or preparations that contain vitamin A.
- you have severe kidney or liver disease or abnormally high levels of fat in your blood
- you are taking methotrexate.

Do not use NOVATRETIN capsules after the expiry date printed on the pack. It may have no effect at all, or worse, an entirely unexpected effect if you take it after the expiry date.

Do not use NOVATRETIN capsules if the packaging is torn or shows signs of tampering. In such case, please return it to your pharmacist or talk to your doctor.

You must tell your doctor if:

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

Taking other medicines

If you are on any other medicine, including medicine bought from a pharmacy, supermarket or health shop, you must tell your doctor.

Some medicines may interfere with NOVATRETIN. These include:

- tetracycline antibiotics (such as Doxine[®], Doxy[®], Achromycin[®] and Minomycin[®])
- phenytoin
- the “mini-pill”, a low-dose progestogen oral contraceptive
- vitamin A, or formulations that contain vitamin A.

Your doctor or pharmacist has an entire list of medicines to be avoided while taking NOVATRETIN.

If you have not told your doctor about any of the above, tell her or him before starting NOVATRETIN capsules.

Take NOVATRETIN capsules exactly as your doctor has prescribed to you.

Use in Children

NOVATRETIN capsules should only be taken by children where alternative therapy cannot be used.

How to take NOVATRETIN capsules

Always take NOVATRETIN exactly as your doctor or pharmacist tells you to.

The directions given may differ from information contained in this leaflet.

How much to take

Take NOVATRETIN capsules exactly as your doctor has prescribed to you.

Your doctor will determine exactly how many NOVATRETIN capsules to take each day for your condition.

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

The starting dose is usually either 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 by your doctor when it is known how you respond to NOVATRETIN capsules.

The initial signs of improvement may be seen in the first week but, more often, after 2 or 3 weeks. It may take 2 to 3 months until the full effect is seen.

Affected skin areas will either peel off or steadily clear. Sometimes more redness or itching may be present at first, but this will normally improve as treatment continues.

How to take it

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

When to take it

NOVATRETIN capsules should be taken once daily with meals or with a glass of milk.

Female patients should wait until the 2nd or 3rd day of their menstrual period before starting NOVATRETIN capsules. This helps to ensure that you are not pregnant before you start to take NOVATRETIN therapy.

How long to take NOVATRETIN

Continue taking NOVATRETIN capsules for as long as your doctor prescribes.

If you forget to take NOVATRETIN

Take it as soon as you remember and then go back to taking it as you would normally.

However, if it is nearly time for your next dose, skip the dose you missed and take your next dose when you are supposed to.

You should not make up for missing the dose by doubling (two doses at the same time) the next dose.

If you are unsure what to do, consult your doctor or pharmacist.

If you have issues remembering your dose, consult your pharmacist who can offer you some hints.

In case of an overdose

Immediately, telephone your doctor or the National Poisons and Hazardous Chemicals Information Centre **(0800 POISON – 0800 764 766)** or go to the Accident and Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too much NOVATRETIN. **Do this even if there are no signs of discomfort or poisoning. You may require urgent medical attention.**

Currently, no information is available on the effects of overdose with NOVATRETIN. In spite of this, based on experience with excessive vitamin A and other drugs similar to NOVATRETIN, 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 but may need some tests to determine if your liver has been affected.

Please keep these telephone numbers handy.

If you are unsure as what to do, ask your doctor or pharmacist.

While you are taking NOVATRETIN

Things you must do:

Tell all doctors, dentists and pharmacists who are treating you that you are on NOVATRETIN capsules.

NOVATRETIN capsules can cause birth defects. This means that you must use strict birth control for at least 1 month before you start NOVATRETIN, the whole time you are using NOVATRETIN capsules and for at least 2 years after you finish taking NOVATRETIN capsules.

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

If you become pregnant while taking NOVATRETIN capsules, stop taking it immediately and inform your doctor. You must also tell your doctor immediately if you become pregnant in the 2 years following the end of treatment.

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

It is critical to keep all of your appointments with your doctor so your progress with NOVATRETIN therapy can be monitored regularly. Your doctor may ask you to do some blood, liver function and other tests from time to time in order to check your progress and pick up any unwanted side effects.

Inform your doctor if you take vitamin supplements that contain greater than 2500 IU of Vitamin A. If you are unsure about this, please check with your doctor or pharmacist.

Consumption of alcohol should be avoided during treatment. Alcohol intake should also be avoided for 2 months after finishing treatment with NOVATRETIN.

Things you must not do:

Do not stop taking NOVATRETIN capsules or change the dose without first checking with your doctor.

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

Do not donate blood while taking NOVATRETIN capsules or for at least 2 years after stopping treatment.

Do not use the “mini-pill”, a low-dose progestogen oral contraceptive, as contraception during treatment.

Do not give NOVATRETIN capsules to anyone else, even if their symptoms seem similar to yours.

Do not use NOVATRETIN capsules to treat other complaints unless told to by your doctor.

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

Things to be careful of

Normally NOVATRETIN capsules would not affect your ability to drive a car or operate machinery. However visual disturbances may occur while taking NOVATRETIN capsules. Make sure you know how you react to NOVATRETIN capsules before you drive a car, operate machinery or do anything else that might be dangerous if your vision is altered.

Wearing contact lenses during treatment and shortly after treatment with NOVATRETIN capsules may cause discomfort. NOVATRETIN capsules cause dry eyes so an eye lubricant, or artificial tears (available from your pharmacist) might be necessary. Otherwise you might need to compensate by wearing your glasses.

Avoid excessive sun exposure, and always apply sunscreen while taking NOVATRETIN capsules. Your skin may be more prone to sunburn while on NOVATRETIN.

Side effects

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

NOVATRETIN helps most people with skin conditions, however in addition to the beneficial effects, it is possible that unwanted side effects will occur in some people during treatment, even when it is used as directed.

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

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

If side effects occur, they may be:

- dryness of the lips, mouth, nose, eyes and skin. Either 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 most likely stop after the dose of NOVATRETIN is lowered or stopped.

Tell your doctor if you have any of the following side effects 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

These side effects are dose related and indicate that the dose of NOVATRETIN needs to be adjusted.

Stop taking NOVATRETIN capsules and contact your doctor immediately if you experience any of the following:

- nausea

- vomiting
- headache
- blurred vision or visual disturbances

This is not an entire list of all possible side effects. Others may arise in some people and there may be some side effects not yet known.

Tell your doctor if you have anything else that is making you unwell. Other side effects not listed above may occur in some people.

Consult your doctor or pharmacist if there is anything you do not understand in this list.

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

After taking NOVATRETIN capsules

Keep your NOVATRETIN capsules in the blister pack until it is time to take them. If you take the capsules out of the packaging they may not keep well.

Keep NOVATRETIN capsules in a cool dry place where the temperature stays below 25°C. Do not keep the capsules, or any other medicine, in a bathroom or near a sink.

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

Both heat and dampness can destroy some medicines.

Protect NOVATRETIN capsules from light.

Keep NOVATRETIN where children cannot reach them.

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

Disposal

If your doctor asks you to stop taking NOVATRETIN, or the capsules have passed their expiry date, you should return any remaining capsules at the end of your treatment to your doctor or pharmacy.

Product description

What it looks like:

NOVATRETIN hard-gelatin capsules can be described as follows:

10 mg Capsules: Hard gelatin capsule containing a yellow powder with a white to off-white body and a brown cap printed in black with "A10" on the capsule body.

25 mg Capsules: Hard gelatin capsule containing a yellow powder with a yellow to light yellow body and a brown cap printed in black with "A25" on the capsule body.

Ingredients:

Active ingredient - acitretin

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

Inactive ingredients -

maltodextrin, sodium ascorbate, microcrystalline cellulose, gelatin, sodium lauryl sulfate, purified water, black printing ink (shellac glaze, iron oxide black (E172), propylene glycol (E1520)) and the colourants iron oxide red (E172), iron oxide yellow (E172) and titanium dioxide.

NOVATRETIN Capsules come in pack sizes of 60s or 100's.

Manufacturer

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