

Novatretin Capsules®

Acitretin (10 mg and 25)

Consumer Medication Information Leaflet (RiMUP)

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What Novatretin Capsules is used for

NOVATRETIN is used to treat severe forms of psoriasis and severe disorders of keratinization

How Novatretin Capsules works

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.

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 Capsules

- *When you must not use it*

Do not take NOVATRETIN capsules if:

- you are pregnant or you intend to become pregnant in the next 36 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 one week 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 four weeks before, during and 3 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 Doxycycline and Minocycline.
- 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.

- *Before you start use it*

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 use it:

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

Women must use effective contraception before, during and after taking Novatretin:

- You must agree to use at least one very reliable method of contraception (for example an intrauterine 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 Novatretin, during treatment and for 3 years after stopping.
- 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 Novatretin

- You must agree to regular follow-up visits, ideally every month
- You must agree to have regular pregnancy tests, ideally every month during treatment and, because some medicine may still be left in your body, every 1 to 3 months for 3 years after stopping Novatretin (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 a 3 years afterwards because some medicine may still be left in your body.

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

Advise for men

The levels of oral retinoid in the semen taking Novatretin 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 you pharmacist at the end of treatment

You should not donate blood during treatment with this medicine and for 3 years after stopping Novatretin because an unborn baby could be harmed if a pregnant patient receives your blood

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 Doxycycline and Minocycline)
- 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 use Novatretin Capsules

- *How much to use*

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 x10mg 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.

An initial worsening of psoriasis symptoms is sometimes seen at the beginning of the treatment period

- *When to use 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 use it*

Continue taking NOVATRETIN capsules for as long as your doctor recommends

- *If you forget to use it*

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.

- *If you use too much (overdose)*

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Symptoms of overdose are headache and vertigo.

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

While you are using it

- *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 four weeks before you start NOVATRETIN, the whole time you are using NOVATRETIN capsules and for at least 3 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 3 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 3 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)
 - Nose bleeding
 - sticky skin may occur
 - hair loss and fragile nail sometimes occurs (and in rare cases, has persisted)
 - rash, ”redness of the skin” or itchiness
 - muscle, joint and bone pain
 - 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
 - diarrhea
 - 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
 - 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.
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 Novatretin Capsules
- Storage
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.

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.

- Disposal
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

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
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.

- MAL number(s):
Novatretin 10 mg Capsules:
MAL16065054CZ

Novatretin 25 mg Capsules:
MAL16065055ACZ

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