

NOVATIN

Acitretin

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about Novatin 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 Novatin 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 Novatin used for

Novatin contains the active ingredient acitretin.

Novatin 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.

Novatin 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,

Novatin helps return the skin to normal.

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

Your doctor may have prescribed Novatin for another purpose.

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

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

Before you take Novatin

Do not take Novatin 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 Novatin.

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

Novatin 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 Novatin.

- you have had an allergic reaction to Novatin, Vitamin A, other retinoids or any ingredients listed in the Ingredients section of this leaflet.
- you are taking tetracycline antibiotics (such as doxycycline HCl: Doryx®, Vibramycin® 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 Novatin 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 Novatin if the package is torn or shows signs of tampering.

If you are not sure if you should be taking Novatin, 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 Novatin. These medicines include:

- tetracycline antibiotics (such as minomycin - Vibramycin®)
- 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 Novatin.

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

Use Novatin exactly as your doctor has prescribed.

Use in Children

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

How to take Novatin

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 Novatin exactly as your doctor has prescribed.

Your doctor will tell you how many Novatin 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

Novatin 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 Novatin therapy.

How long to take Novatin

Continue taking Novatin until your doctor tells you to stop.

If you forget to take Novatin

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) 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 Novatin. 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 Novatin. However, based on experience with excessive vitamin A and other drugs similar to Novatin, 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 Novatin

Things you must do

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

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 Novatin 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 Novatin.

FOR FEMALE PATIENTS:

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

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

Stop taking Novatin immediately and tell your doctor if you do become pregnant while you are taking Novatin. 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 Novatin 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 Novatin to anyone else even if their symptoms seem similar to yours.

Do not use Novatin 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 Novatin, 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 Novatin 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 Novatin.

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

Side effects

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

Novatin 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 Novatin 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 Novatin needs to be adjusted.

Stop taking Novatin 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 Novatin

Keep your tablets/capsules/ syrup in the pack/bottle until it is time to take them.

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

Keep Novatin 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 Novatin from light.

Keep Novatin 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 Novatin, 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 Novatin looks like

10 mg capsule: 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. AUST R 196006

25 mg capsule: 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. AUST R 196003

Available in blister packs of 60 and 100 capsules.

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each capsule contains 10 or 25 mg of acitretin as the active ingredient.

It also contains the following:

- maltodextrin
- sodium ascorbate
- microcrystalline cellulose
- gelatin
- sodium lauryl sulphate
- purified water
- black printing ink (shellac glaze, iron oxide black (E172), propylene glycol (E1520))
- iron oxide red (E172) (colourant)
- iron oxide yellow (E172) (colourant) for 25 mg capsules only
- titanium dioxide

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

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