

ACNOTIN CAPSULE

Isotretinoin (10mg, 20mg)

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What Acnotin is used for

Acnotin is used to treat severe types of acne (such as acne that is at risk of causing permanent scarring).

You will use Acnotin when your acne has not got better with anti-acne treatments, including antibiotics and skin treatments.

Acnotin treatment must be supervised by a skin specialist.

How Acnotin works

Acnotin belongs to a group of medicines called retinoids, which are similar to vitamin A.

The retinoids work by reducing the amount of the oily substance (i.e. sebum) made by glands in your skin, reducing bacteria, reducing inflammation and opening clogged pores

Before you use Acnotin

WARNING

CAN SERIOUSLY HARM AN UNBORN BABY

Women must use effective contraception.

Do not use if you are pregnant or think you may be pregnant.

- When you must not use it

Do not use Acnotin if;

1. You are pregnant or you plan to become pregnant, or if there is any chance you could become pregnant.

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

- 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 Acnotin, during treatment and for a month afterwards.
- 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 Acnotin:

- You must agree to regular followup visits, ideally every month.
- You must agree to have regular pregnancy test, ideally every month during treatment and, 1 month after stopping Acnotin because some medicine may still be left in your body (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 month afterwards because some medicine may still be left on your body.

If you get pregnant while taking Acnotin, stop taking the medicine straight away and contact your doctor. Also, if you become pregnant within one month after you stop taking Acnotin, you should contact your doctor.

Advice for men

The levels of oral retinoid in the semen of men taking Acnotin are too low to harm their partners' unborn baby.

However, you must never share your medication with anyone, especially females.

Additional precautions

1. You should never give this medicinal product to another person. Please take any unused capsules to your pharmacist at the end of treatment.
2. You should not donate blood during treatment with this medicine and for 1 month after stopping Acnotin because an unborn baby could be harmed if a pregnant woman receives your blood.
3. You are breastfeeding. Breastfeeding must stop before treatment begins. Do not breastfeed while taking Acnotin.
4. You have had an allergic reaction to Isotretinoin, vitamin A, other retinoids or soya or any other ingredients of Acnotin (listed at the end of this leaflet).
5. You are taking tetracycline antibiotics.
6. You have liver and kidney disease.
7. You have very high fat levels (cholesterol, triglycerides) in your blood.
8. You have vitamin A toxicity caused by an excessive amount of vitamin A in the diet.
9. The packaging is torn or shows signs of tampering.
10. The expiry date (EXP) printed on the pack has passed. If you take this medicine after the expiry date has passed, it may not work as well.

If you are not sure if you should start taking Acnotin, contact your doctor.

- Before you start to use it

Mental health problems

Your mood may be affected while taking Acnotin. You may not notice some changes in your mood and behavior and so it is very important that you tell your friends and family that you are taking this medicine. They may notice these changes and help you quickly identify any problems that you need to talk to your doctor.

You must tell your doctor if:

1. You have any allergies to any other medicines, foods, preservatives or dyes

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2. You have or have had any other health problems or issues including:

- diabetes, or a history of diabetes in your family
- depression
- liver disease
- kidney disease
- lipid (cholesterol or triglyceride) disorder

3. You drink large amounts of alcohol.

- Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription, from a pharmacy, supermarket or health food shop. Some medicines may interfere with Acnotin. These include:

- tetracycline antibiotics
- vitamin A, or preparations containing vitamin A (including vitamin supplements)
- the "mini-pill", a progestogen only oral contraceptive pill.

These medicines may be affected by Acnotin, or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Acnotin.

Ask your doctor or pharmacist if you are not sure about this list of medicines.

How to use Acnotin

- How much to use

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

They may differ from the information contained in this leaflet.

Your doctor will tell you how many Acnotin capsules to take each day. The dose ranges from 0.5 to 2mg/kg body weight per day. This dose will be calculated to suit your individual needs and your body weight. This dose may be adjusted during treatment when the doctor knows how you respond to Acnotin.

- When to use it

Take Acnotin once or twice a day and must always be taken with meals.

Capsules should be swallowed whole with a glass of water.

Do not open the capsules and do not take any capsules that are damaged.

Women should wait until the 2nd or 3rd day of the next normal menstrual period before starting Acnotin treatment.

This helps ensure that you aren't pregnant before you start taking Acnotin

- How long to use it

Continue taking Acnotin for as long as your doctor prescribes. Acne treatment with Acnotin will usually last 4 to 6 months. In the initial treatment your acne may get a little worse before it gets better. Do not worry about this, it is a sign that Acnotin is working. At the end of this treatment your acne should have cleared up significantly. Most people notice their skin condition continues to improve up to two months even after Acnotin treatment is finished.

- If you forget to use it

Do not try to make up for missed doses by taking an extra dose.

This may increase the chance of getting an unwanted side effect.

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

If you have missed several doses, please inform your doctor and follow the advice given to you.

- If you use too much (overdose)

Symptoms of vitamin A toxicity could appear in cases of overdose e.g. abdominal pain, dizziness, headache, severe nausea, vomiting, irritability, itchy skin. You may need urgent medical attention. Contact your doctor or visit the nearest Accident & Emergency Department immediately (bring along the medication, carton and this leaflet if possible).

While you are using Acnotin

- Things you must do

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

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.

Tell your doctor if you feel Acnotin capsules are not helping your condition.

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

Your doctor may ask you to have regular blood tests to monitor your liver function, blood sugar levels and blood cholesterol levels.

If you are intending to do a lot of heavy lifting or exercise, tell your doctor.

Your muscles and joints may be more prone to tenderness or stiffness if you do a lot of heavy exercise while taking Acnotin.

Talk to your doctor if you experience persistent pain in your lower back or buttocks during treatment with Acnotin. These symptoms may be signs of sacroiliitis, a type of inflammatory back pain. Your doctor may discontinue treatment with Acnotin and refer you to a specialist for treatment of inflammatory back pain. Further evaluation may be needed including imaging modalities such as MRI.

- Things you must not do

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

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

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

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

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- Things to be careful of

Be careful driving or operating machinery until you know how Acnotin affects you.

Normally Acnotin would not affect your ability to drive a car or operate machinery. However eye discomfort due to light and other visual disturbances may occur when taking Acnotin. Make sure you know how you react to Acnotin before you drive a car, operate machinery or do anything else that may be dangerous if your vision is affected.

Dental problems can occur resulting from dryness of mouth and may increase dental disease, including tooth decay, gum disease and fungus infections: regular dental appointments are needed and use of sugarless candy or saliva substitute or melting ice in mouth may be necessary to lessen dental problems.

Wearing contact lenses during treatment with Acnotin may cause discomfort.

Acnotin may cause dry eyes. An eye lubricant or artificial tears, available from your pharmacist, should relieve this problem. Otherwise, you may temporarily need to wear your lenses for shorter periods or wear glasses instead.

Avoid excessive sun exposure and UV rays and apply a sunscreen of at least SPF15 while taking Acnotin. Your skin may be more prone to sunburn while on Acnotin.

Avoid waxing, skin lasers and skin exfoliation while taking Acnotin and for 5 to 6 months after stopping Acnotin treatment.

Your skin may be more sensitive while on Acnotin. It may cause skin inflammation and scarring.

Side effects

Acnotin helps most people with acne but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of

medical treatment if you get some of the side effects.

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

Some of the side effects associated with the use of Acnotin are dose related. The side effects are generally reversible after altering the dose or discontinuation of treatment, however, some may persist after treatment has stopped.

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

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

- Vitamin A toxicity
 - Dry skin, eyes, mucous layer
 - Red and clouding of eyes
- Skin disorder
 - Skin irritations, rash
 - Skin inflammations
 - Sweating
 - Skin sensitivity
 - Hair thinning
 - Scalling
 - Redness
 - Burning
 - Pain and other signs of inflammation of lips
- Musculo-skeletal disorders
 - Muscle pain
 - Joint pain
 - Persistent pain in the lower back or buttocks
- Renal and urinary disorders
 - Inflammation of urethra
- Psychiatric disorders
 - Depression
 - Suicide attempt
 - Headache
 - Seizure
 - Behavioral disorders
- Sensory disorders
 - Impaired hearing
 - Eye discomfort due to light
- Gastrointestinal disorders
 - Nausea
 - Bowel inflammation
- Liver disorders
 - Increase in liver enzymes
- Respiratory disorders
 - Difficulty to breathe
- Blood disorders
 - Decrease in red and white blood cell count

- Changes in platelet

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.

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 Acnotin

- Storage

Store below 30°C in a dry place. Protect from heat and direct light. Keep out of reach of children.

- 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

Acnotin 10: Orange color oily suspension filled in oval, opaque purple color soft gelatin capsule.

Acnotin 20: Orange color oily suspension filled in oval, opaque purple and white color soft gelatin capsule.

- Ingredients

- Active Ingredients:

Acnotin 10: Each softgel capsule contains: Isotretinoin 10 mg

Acnotin 20: Each softgel capsule contains: Isotretinoin 20 mg

- Inactive Ingredients

Acnotin 10:

Disodium EDTA, Carmoisine (CI14720), Iron Oxide Black CI77499, Butylated

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Hydroxyanisole, Ponceau 4R
Lake (C.I. No.16255), Titanium
Dioxide, Soybean Oil (Glycine
soja), Glycerin, Sorbitol Solution
70% (noncrystallising), Vegetable
oil partial Hydrogenated, Gelatin,
Purified Water (Aqua), White Wax
NF, brilliant blue CI 42090

Acnotin 20:

Disodium EDTA, Carmoisine,
Iron Oxide Black, Butylated
Hydroxyanisole, Ponceau 4R,
Gelatin, Purified Water (Aqua),
White Wax, Soybean Oil,
Glycerin, Sorbitol Solution 70%
(non crystallising), Vegetable oil
partial Hydrogenated, Titanium
dioxide (E 171), Brilliant blue\

- MAL number:

Acnotin 10mg: MAL06021192AZ

Acnotin 20mg: MAL06021200AZ

Manufacturer

Mega Lifesciences Public Company
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Product Registration Holder

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