

Isotretinoin AN capsules

Isotretinoin

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Isotretinoin AN 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 Isotretinoin AN capsules against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What Isotretinoin AN is used for

Isotretinoin AN capsules contains the active ingredient isotretinoin.

Isotretinoin AN is used to treat acne.

Isotretinoin AN 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.

There are many different types of medicines used to treat acne. Isotretinoin AN is used for more severe cases.

Your doctor, however, may have prescribed Isotretinoin AN for another purpose.

Ask your doctor if you have any questions about why isotretinoin AN has been prescribed for you.

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

Isotretinoin AN is not addictive.

Before you take Isotretinoin AN

When you must not take Isotretinoin AN

1. you are pregnant, or for at least one month before you plan to fall pregnant
If you fall pregnant while taking Isotretinoin AN there is an extremely high risk of having a baby that is severely deformed. You must use effective contraception for one month before, during and one month after treatment.
2. you are breastfeeding
Breastfeeding must stop before treatment begins. Do not breastfeed while taking Isotretinoin AN.

Do not take Isotretinoin AN if:

- 3. you have had an allergic reaction to Isotretinoin AN, vitamin A, other retinoids or any other ingredients of Isotretinoin AN (listed at the end of this leaflet)**
- 4. you are taking tetracycline antibiotics (such as Akamin®, Vibramycin®, Doxycycline hydrochloride, Doryx®, Frakas®, Minomycin®)**
- 5. you have severe liver disease**
- 6. you have very high fat levels (cholesterol, triglycerides) in your blood**

7. you have hypervitaminosis A.

This is a condition caused by an excessive amount of vitamin A in the diet.

8. the packaging is torn or shows signs of tampering

9. 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 Isotretinoin AN contact your doctor.

Do not give Isotretinoin AN to children.

There is limited information on the use of Isotretinoin AN in children before puberty.

Before you start to take Isotretinoin AN

Tell your doctor if:

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

Isotretinoin capsules contain soya oil, which may contain traces of arachidic acid (a component of peanut oil)

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
- hormone disorder
- stomach or bowel disease

3. you drink large amounts of alcohol.

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

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 Isotretinoin AN. These include:

- tetracycline antibiotics (such as Akamin, Doxycycline hydrochloride, Frakas, Vibramycin, Doryx, Minomycin)
- vitamin A, or preparations containing vitamin A (including vitamin supplements)
- other medicines you are using to treat your acne
- the "mini-pill", a progestogen-only oral contraceptive pill.

These medicines may be affected by Isotretinoin AN, 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 Isotretinoin AN.

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

How to take Isotretinoin AN

How much to take

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

They may differ from the information contained in this leaflet.

Take Isotretinoin AN exactly as your doctor has prescribed.

Your doctor will tell you how many Isotretinoin AN capsules to take each 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 Isotretinoin AN.

How to take Isotretinoin AN

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

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

When to take Isotretinoin AN

Isotretinoin AN may be taken once or twice a day and must always be taken with meals.

Female patients should wait until the 2nd or 3rd day of the next normal menstrual period before starting Isotretinoin AN treatment.

This helps ensure that you aren't pregnant before you start taking Isotretinoin AN.

If you forget to take Isotretinoin AN

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.

How long to take Isotretinoin AN for

Continue taking Isotretinoin AN for as long as your doctor prescribes.

Acne treatment with Isotretinoin AN will usually last 4 to 8 months. In the first few weeks of treatment your acne will probably get a little worse before it gets better.

Do not worry about this, it is a sign that Isotretinoin AN is working.

At the end of this time your acne should have cleared up significantly. Most patients notice their skin condition continues to improve even after Isotretinoin AN treatment is finished. Please note that Isotretinoin AN cannot improve scars or pitting that were present before treatment started, but it will help prevent such skin damage in the future.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Isotretinoin AN. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Signs of overdose include transient headache; vomiting; facial flushing;

reddened, cracked lips; stomach pain; headache; dizziness and unsteady walking.

Keep telephone numbers for these places handy.

While you are taking Isotretinoin AN

Things you must do

If you become pregnant while taking Isotretinoin AN, stop taking it and tell your doctor immediately.

Isotretinoin AN can cause birth defects (damage to unborn babies). You must use strict birth control, starting at least 1 month before you begin taking Isotretinoin AN, for the whole time you are taking Isotretinoin AN and for 1 month after you finish taking Isotretinoin AN.

There is no known risk to males who wish to father children.

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

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 Isotretinoin AN 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 Isotretinoin AN.

Things you must not do

Do not stop taking Isotretinoin AN 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 Isotretinoin AN to anyone else even if their symptoms seem similar to yours.

Do not use Isotretinoin AN to treat other complaints unless your doctor says to.

Do not donate blood during treatment with Isotretinoin AN or for at least 1 month after stopping treatment.

Things to be careful of

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

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

Wearing contact lenses during treatment with Isotretinoin AN may cause discomfort.

Isotretinoin AN 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 solariums and apply a sunscreen while taking Isotretinoin AN.

Your skin may be more prone to sunburn while on Isotretinoin AN.

Avoid waxing and dermabrasion while taking Isotretinoin AN and for 5 to 6 months after stopping Isotretinoin AN treatment.

Your skin may be more sensitive while on Isotretinoin AN. Waxing may cause dermatitis and dermabrasion may cause scarring during and for several months after Isotretinoin AN treatment.

Avoid using facial peels, electrolysis and some hair treatments.

Your skin and hair may be more delicate during treatment and for a while after Isotretinoin AN treatment.

Side Effects

Isotretinoin AN 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 the time they are not. You may need 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.

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:

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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:

- dryness of the lips, mouth, nose and skin
A moisturiser or petroleum jelly can be used to soften the lining of the nose, lips and the skin areas not affected by the acne
- fragile skin
- change in colour of the skin
- peeling palms of the hands and soles of the feet
- itchy skin rash
- an increased susceptibility to sunburn
- sweating
- changes to the nails
- eye problems such as dry, sore, swollen or itchy eyes, discharge or trouble seeing at night
- nosebleeds
- tenderness or stiffness in your bones, joints or muscles
- tiredness headache
- hair loss (sometimes occurs and is usually temporary but in rare cases, has persisted)
- excessive hairiness
- hoarseness.

These side effects are usually mild and dose related. Most of them disappear completely in a few days to a few weeks after the dose of Isotretinoin AN is lowered or stopped.

Tell your doctor immediately if you experience any of the following:

- nausea
- vomiting
- persistent headache
- blurred vision or visual disturbances
- changes in your hearing or ringing in your ears
- severe upper stomach pain
- blood in stools or severe diarrhoea
- severe bruising
- sudden red, often itchy spots, similar to the rash of measles starting on the face, hands or feet
The spots may blister or change to flat round raised, red, pale-centred marks. Also, you may have fever, sore throat, headache and/or diarrhoea.
- painful red areas, that change to large blisters and end with peeling of layers of skin, that may occur on lips, mouth, eyes, nose and genitals. Those affected may have fever and chills, aching muscles and generally feel unwell.
- thinking, seeing or hearing things that are not real
- feeling depressed, with or without suicidal thoughts

Symptoms of depression may include:

- feeling sad or having crying spells
- losing interest in activities you once enjoyed
- sleeping too much or having trouble sleeping
- changes in your appetite or body weight
- having trouble concentrating
- withdrawing from your friends or family
- feeling like you have no energy
- feelings of worthlessness or inappropriate guilt.

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

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.

After taking Isotretinoin AN

Storage

Keep your capsules in the blister pack until it is time to take them.

If you take the capsules out of the packaging they will not keep well.

Keep the blister pack in a cool dry place where the temperature stays below 25°C.

Do not store Isotretinoin AN, 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.

Keep Isotretinoin AN where young children cannot reach it.

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

Protect Isotretinoin AN from light.

Disposal

If your doctor tells you to stop taking Isotretinoin AN, or your capsules have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Isotretinoin AN 10 mg & 20 mg isotretinoin) are presented in pack sizes of 15, 30, 60 & 90 capsules in blister.

Isotretinoin AN 10 mg (AUST R 186339)
Light violet coloured oblong soft gelatin capsules, containing a yellow-orange opaque viscous liquid.

Isotretinoin AN 20 mg (AUST R 186340)
Maroon coloured oblong soft gelatin capsules, containing a yellow-orange opaque viscous liquid.

Ingredients

Active Ingredient:

Isotretinoin

Each capsule may contain either 10 mg & 20 mg of isotretinoin

Other Ingredients:

- yellow beeswax
- brilliant scarlet 4R
- butylated hydroxyanisole
- disodium edetate
- di-alpha-tocopherol
- gelatin
- glycerol
- sorbitol solution (70 per cent) (non-crystallising)
- soya oil
- partially hydrogenated soya oil
- titanium oxide
- hydrogenated vegetable oil
- purified water.

Isotretinoin AN 10 mg contains black iron oxide.

Isotretinoin AN 20 mg contains indigo carmine.

Please read this leaflet carefully before you start taking Isotretinoin AN. You may wish to keep it to read again.

Name and Address of the Sponsor

Amneal Pharma Australia Pty Ltd
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