

APO-Isotretinoin

Isotretinoin

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 isotretinoin. 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 using this medicine 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 want to read it again.

What this medicine is used for

Isotretinoin is used to treat severe acne, where other treatments have not worked.

It belongs to a group of medicines called retinoids, which are like Vitamin A.

How it works

Isotretinoin works by reducing the amount of the oil (sebum) made by glands in your skin. It also reduces bacteria and inflammation and helps to open clogged pores.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed this medicine for another reason.

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

This medicine is not addictive.

There is not enough information to recommend the use of this medicine in children.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- isotretinoin
- vitamin A
- other retinoids
- soya
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin

Do not take this medicine if you are pregnant, or for at least one month before you plan to fall pregnant.

If you fall pregnant while taking this medicine, 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.

Do not take this medicine if you are breastfeeding.

This medicine passes into breast milk and your baby may be affected.

Do not take this medicine if you are taking tetracycline antibiotics (e.g. doxycycline, minocycline).

Do not take this medicine if you have the following medical conditions:

- severe liver disease
- very high fat levels (cholesterol, triglycerides) in your blood
- hypervitaminosis A

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

If you have a peanut allergy, discuss with your doctor the risks and benefits of taking this product.

Some people who are allergic to peanuts may also be allergic to the soya oil in these capsules.

In addition, the soya oil in this product is manufactured in a facility which produces other products containing peanut oil. It cannot be guaranteed that this product does not contain traces of peanut oil.

Tell your doctor if you have or have had any of the following medical conditions:

- diabetes or a family history of diabetes
- high fat (lipid) levels or a family history of lipid disorders
- kidney problems
- stomach or bowel disease
- excessive body weight or a family history of obesity
- depression or a history of depression

Tell your doctor if you drink large amounts of alcohol or you smoke.

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

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interact with isotretinoin. These include:

- tetracycline antibiotics (e.g. doxycycline, minocycline)
- vitamin A, or preparations containing vitamin A
- other acne treatments (e.g. strong creams, ointments or gels)
- the 'mini-pill', a progestogen-only oral contraceptive pill
- contraceptives containing norethisterone or norethisterone acetate
- phenytoin, used to treat epilepsy
- oral or injectable corticosteroids

These medicines may be affected by this medicine or may affect how well it works. You may need different

amounts of your medicines, or you may need to take different medicines.

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

Other medicines not listed above may also interact with isotretinoin.

How to take this medicine

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

They may differ to the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how much of this medicine you should take, depending on your body weight and how well you respond to isotretinoin.

How to take it

Swallow the capsules whole with a glass of water or milk.

Do not open the capsules or take any capsules that are damaged.

When to take it

Take this medicine at about the same time each day, either once or twice a day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

Isotretinoin must always be taken with food.

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

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

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

Isotretinoin treatment usually lasts around four months. In some cases a second course may be needed, usually with a gap of two months between courses.

In the first few weeks of treatment your acne may worsen, but this will usually stop within seven to ten days. This is a sign that isotretinoin is working.

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

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose, skip the dose you missed and take your next dose at the usual time.

Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

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 your nearest hospital if you think that 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.

If you take too much isotretinoin you may experience a severe but short-lived headache, nausea, vomiting, facial flushing, reddened lips, stomach pain, drowsiness, irritability, itching, dizziness or unsteady walking.

For one month following an overdose:

- you must not donate blood
- females must not become pregnant
- males must not father a child, as there is a chance that isotretinoin may be present in higher levels in semen.

While you are taking this medicine

Things you must do

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

Isotretinoin causes birth defects in females taking isotretinoin.

You must use strict birth control for at least 1 month before, during and for 1 month after taking isotretinoin.

There is no known risk to males who wish to father children (except after overdosing; see previously).

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking this medicine.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Tell your doctor if you are about to have any blood tests.

Tell your doctor if you are planning to do a lot of vigorous exercise while taking isotretinoin.

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

Tell your doctor if you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

Things you must not do

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not take your medicine to treat any other complaint unless your doctor tells you to.

Do not stop taking your medicine or change the dosage without first checking with your doctor.

Do not donate blood during treatment with isotretinoin or for at least four weeks after stopping treatment.

Things to be careful of

Tell your doctor if your skin condition does not improve within one to two months of starting this medicine, or if your skin irritation becomes severe.

During the first three weeks of taking isotretinoin, your skin may become irritated. Your acne may seem to get worse before it gets better.

Full improvement continues after you stop taking isotretinoin and may take up to six months.

If you develop any new skin rash (e.g. redness, hives, spots, blisters or flaking skin) during isotretinoin treatment, contact your doctor immediately.

There have been reports of skin rash associated with this medicine. Some of these rashes may be serious and can cause severe illness. These serious rashes may be accompanied or preceded by flu-like symptoms.

Isotretinoin may cause hearing problems in one or both ears (ringing in the ears, unable to hear certain sounds, deafness).

This may occur during or after finishing a course of isotretinoin. No more isotretinoin should be taken, and medical attention sought immediately.

Isotretinoin may cause bowel problems. Contact your doctor immediately if you have severe stomach pains, bleeding from the rectum or bloody diarrhoea.

Isotretinoin may cause dryness of the mouth and nose.

For temporary relief of mouth dryness, use sugarless candy or gum, melt bits of ice in your mouth, or use a saliva substitute. However, if dry mouth continues for more than two weeks, check with your doctor or dentist. Continuing dryness of the mouth may increase the chance of dental disease, including tooth decay and gum disease. Moisturiser or petroleum jelly can be used to soften the lining of the nose, lips and the skin areas not affected by acne.

Isotretinoin may cause mood or behaviour problems, including having thoughts about self-harm or suicide. Tell your doctor immediately if unusual mood or behaviour problems occur.

Symptoms of depression may include:

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

Isotretinoin may cause bone or muscle problems, including joint

pain, muscle pain or stiffness, or difficulty moving. Tell your doctor if these problems are bothersome.

Your doctor will monitor you for signs of raised lipid (fat) levels in your blood.

You may be able to manage these with diet, weight loss, restricting alcohol intake and stopping smoking. Tell your doctor straight away if you have severe pains in your upper abdomen.

This medicine may affect blood sugar levels.

Tell your doctor if you have diabetes and you notice a change in the results of blood or urine sugar tests.

Isotretinoin may cause dry eyes.

Wearing contact lenses during treatment with isotretinoin may cause discomfort. You may temporarily need to wear your lenses for shorter periods or wear glasses instead. An eye lubricant or artificial tears, available from your pharmacist, should relieve this problem. Make sure your doctor or eye specialist know if you have dry eyes, so they can monitor you.

Eye infections, inflammation and hazy vision may also occur and should be monitored closely by your doctor and eye specialist.

Your skin will be more prone to sunburn, dryness, or irritation, especially during the first two or three weeks of treatment. It is advised to:

- avoid excessive exposure to the sun, UV, sunlamp or solarium, wind or cold weather
- use sunscreen with at least SPF15
- wear protective clothing and hats
- use skin moisturiser and lip balm

Avoid waxing, dermabrasion and laser treatment while taking isotretinoin and for five to six months after stopping isotretinoin.

Your skin may be more sensitive while on isotretinoin. Waxing may cause dermatitis and dermabrasion may lift the skin's surface and cause

scarring during and for several months after isotretinoin therapy.

Avoid using facial peels, electrolysis and some hair treatments.

Your skin and hair may be more delicate during treatment and for a while after taking isotretinoin. Using mild creams and ointments may help.

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

Isotretinoin usually does not affect your ability to drive a car or operate machinery. However, altered night vision and other visual disturbances may occur when taking isotretinoin. Some people may also feel drowsy or dizzy. Make sure you know how you react to isotretinoin before you drive a car, operate machinery or do anything else that may be dangerous.

Side effects

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

This medicine helps most people with severe acne but 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 attention if you get some of the side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

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

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

- dry lips (scaling, redness, burning, pain or other signs of inflammation), mouth, nose and skin (including rash)
- nosebleeds

- peeling palms of the hands and soles of the feet
- nail infection or inflammation
- dry throat or hoarse voice
- infections e.g. cold sores
- muscle, back or tendon pain or stiffness
- bleeding or red, swollen gums
- feeling lethargic, tired or having no energy
- mild headache
- feeling dizzy, drowsy or nervous
- weight loss
- abnormal periods
- feeling sick (nausea)
- sweating, flushing
- bony growths
- itchy skin, bruising, mild rash or peeling, change in skin colour
- an increased chance of sunburn
- initial worsening of acne
- hair loss (usually temporary but has persisted in rare cases)
- changes in hair growth.

The above list includes the more common side effects. Mostly, these are mild.

Tell your doctor as soon as possible if you notice any of the following:

- eye problems (burning, redness, itching or other signs of eye inflammation or infection); problems wearing contact lenses
- loss of appetite, dark urine, pale stools, yellowing of the skin or eyes (jaundice), bleeding or bruising more easily than normal (signs of liver disease)
- bloody or cloudy urine
- severe diarrhoea
- chest infection
- swollen or itchy veins
- frequent infections, fever, severe chills, sore throat or mouth ulcers
- tenderness or stiffness in your bones or joints, fractures
- sleep problems
- blurred or unusual vision

- a change in your blood glucose levels, especially if you are diabetic
- wounds not healing properly

The above list includes serious side effects. You may need medical attention.

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to Accident and Emergency at your nearest hospital:

- shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; muscle pain or tenderness or joint pain or rash, itching or hives on the skin (signs of an allergic reaction)
- severe skin reactions with painful red areas, large blisters, peeling of skin layers; fever, chills, aching muscles, feeling unwell (signs of erythema multiforme, Stevens-Johnson Syndrome or toxic epidermal necrolysis)
- severe diarrhoea, rectal bleeding, black, bloody or tarry stools
- severe pain in your upper stomach spreading to your back, nausea, vomiting, fast heart rate
- brown or dark coloured urine, with severe muscle aching and weakness (signs of muscle breakdown)
- sudden and severe headache or pain behind your eyes, nausea, vomiting
- hearing problems, hearing loss, or ringing in your ears
- psychosis, hallucinations (thinking, seeing or hearing things that are not there)
- feeling anxious or agitated, or acting aggressively
- seizures
- fast or unusual heart rate, fainting
- feeling unable to think and judge clearly
- changing emotions or mood, including crying, self-harm,

thoughts of suicide, attempting suicide

- feeling depressed, with or without suicidal thoughts

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may occur in some patients.

Storage and disposal

Storage

Keep your medicine in the pack until it is time to take it.

If you take your medicine out of the pack it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C. Protect this medicine from light and moisture.

Do not store your medicine or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep this medicine where 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 this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine leftover.

Product description

What it looks like

10 mg capsules: Red-orange, size 3, oval, soft gelatin capsules marked P10. AUST R 190940.

20 mg capsules: Red-orange, size 6, oval, soft gelatin capsules marked P20. AUST R 190941.

Available in blister strips of 60 capsules.

* Not all strengths may be available.

Ingredients

Each capsule contains 10 mg or 20 mg of isotretinoin as the active ingredient.

It also contains the following:

- soya oil
- beeswax - yellow
- soya oil - hydrogenated and partially hydrogenated
- gelatin
- glycerol
- titanium dioxide
- ferrous oxide red
- ferrous oxide yellow
- brilliant blue FCF
- shellac

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

Sponsor

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