

APO-Isotretinoin

Contains the active ingredient isotretinoin

Consumer Medicine Information

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

What is in this leaflet

Read this leaflet carefully before taking your medicine.

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.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up-to-date leaflet from www.apotex.com.au.

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.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Isotretinoin. It contains the active ingredient isotretinoin.

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

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.

How it works

Isotretinoin 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 is used for more serious cases.

Use in children

Do not give isotretinoin to children.

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

This medicine should not be used in children.

Before you take this medicine

When you must not take it

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.
 - **You are breastfeeding.** Breastfeeding must stop before treatment begins. Do not breastfeed while taking this medicine.
 - **Do not take this medicine if you are taking tetracycline antibiotics (such as Vibramycin®, Doryx®, Minomycin®).**
 - **Do not take this medicine if you have severe liver disease.**
 - **Do not take this medicine if you have very high fat levels (cholesterol, triglycerides) in your blood.**
 - **Do not take this medicine if you have hypervitaminosis A** This is a condition caused by an excessive amount of Vitamin A in your diet.
 - **You have had an allergic reaction to Isotretinoin, Vitamin A, other retinoids, soya or any of the ingredients listed at the end of this leaflet.** Symptoms of an allergic reaction may include cough, 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; fainting or hayfever-like symptoms.
3. **You have or have had any medical conditions, especially the following:**
 - diabetes, or a history of diabetes in your family
 - 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.
 4. **You drink large amounts of alcohol, or you smoke.**
 5. **You plan to become pregnant or breastfeed.**
 6. **You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.**

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

Some medicines may interact with isotretinoin. These include:

- tetracycline antibiotics (such as Vibramycin®, Doryx®, Minomycin®). You must not take tetracyclines whilst taking isotretinoin.
- vitamin A, or preparations containing vitamin A, which should be avoided when taking isotretinoin to minimise the chance of side effects
- other medicines (including strong creams, ointments or gels) you are using to treat your acne
- other vitamins, herbal products, or medicines. Some of these medicines (e.g. St. John's Wort) or nutritional supplements may make your birth control pills not work.
- the "mini-pill", a progestogen-only oral contraceptive pill
- contraceptives containing norethisterone or norethisterone acetate
- phenytoin, used mainly to treat epilepsy
- corticosteroids, when taken by mouth or injection

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with isotretinoin.

How to take this medicine

Follow carefully all directions given to you by your doctor or pharmacist. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor will tell you how much of this medicine you should take.

This dose will be calculated to suit your individual needs and your body weight.

This dose may be adjusted during therapy when the doctor knows how you respond to isotretinoin.

How to take it

Swallow the capsules 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 it

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

If you are female, you 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.

Take this medicine at the same time each day.

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

How long to take it for

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

Acne treatment with isotretinoin will usually last around four months, and in some cases a second course lasting four months may be needed, usually with a gap of two months between courses.

In the first few weeks of treatment your acne will probably get a little worse, but this will usually stop getting worse within seven to ten days. Do not worry about this, it 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.

Please note that isotretinoin cannot improve scars or pitting that were present before treatment started, but it will help prevent such skin damage in the future.

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 missed dose 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 to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

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 or vomiting, facial flushing, reddened lips, stomach pain, drowsiness, irritability, itching, dizziness and/or unsteady walking.

You must not donate blood for one month after taking an overdose of isotretinoin, females must not become pregnant for one month, and for one month males must avoid the possibility of making a female pregnant, as there is a chance that isotretinoin may be present in higher levels in semen, following an overdose.

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 starting at least 1 month before you begin taking isotretinoin, for the whole time you are taking isotretinoin and for one month after you finish taking isotretinoin.

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

Tell your doctor that you are taking this medicine if:

- **you are pregnant or are planning to become pregnant**
- **you are breastfeeding or are planning to breastfeed**
- you are about to be started on any new medicine
- you are about to have any blood tests
- you are planning to do a lot of vigorous exercise.

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

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.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

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

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours
- Take your medicine to treat any other condition unless your doctor or pharmacist tells you to
- 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

During the first three weeks of taking isotretinoin, your skin may become irritated. Also, your acne may seem to get worse before it gets better. Check with your doctor if your skin condition does not improve within one to two months of starting this medicine or at any time your skin irritation becomes severe. Full improvement continues after you stop taking isotretinoin and may take up to six months. Your health care professional can help you choose the right skin products to reduce skin dryness and irritation.

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, so if you have severe stomach pains or bleeding from the rectum, or bloody diarrhoea, see your doctor right away.

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, gum disease, and fungus infections.

Isotretinoin may cause mood or behaviour problems, including having thoughts about self-harm or suicide; check with your doctor right away if unusual mood or behaviour problems occur.

Isotretinoin may cause bone or muscle problems, including joint pain, muscle pain or stiffness, or difficulty moving. Check with 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. However if you have severe pains in your upper abdomen (which may be due to raised lipid levels) see your doctor straight away.

For diabetic patients:

This medicine may affect blood sugar levels. If you notice a change in the results of your blood or urine sugar tests or if you have any questions, check with your doctor.

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.

Isotretinoin may cause dry eyes. 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.

Avoid excessive exposure to the sun (or UV, sunlamp or solarium), wind or cold weather. Your skin will be more prone to sunburn, dryness, or irritation, especially during the first two or three weeks of treatment.

Use sunscreen or sun blocking lotions with a sun protection factor (SPF) of at least 15. Also, wear protective clothing and hats. Also use a skin moisturiser and a lip balm to prevent the skin and lips becoming dry.

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. You may use mild creams and ointments to help with this. Your doctor or pharmacist can advise you.

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

Normally isotretinoin 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. 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 if you are affected by isotretinoin.

Possible side effects

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

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

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

This list includes the more common side effects. Mostly, these are mild:

- dry lips (scaling, redness, burning, pain or other signs of inflammation), mouth, nose and skin (including rash). 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
- 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 skin rash or peeling, change in skin colour
- an increased chance of sunburn
- a worsening of acne. This often happens at the beginning of treatment but subsides after a few weeks.
- hair loss (sometimes occurs and is usually temporary but in rare cases, has persisted)
- changes in hair growth.

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

These may be serious side effects. You may need medical attention. Most of these side effects are rare.

- eye problems (burning, redness, itching or other signs of eye inflammation or infection); problems wearing contact lenses
- loss of appetite, dark urine, clay-coloured stools, jaundice (yellowing of the skin or eyes), bleeding or bruising more easily than normal
- bloody or cloudy urine
- severe diarrhoea
- chest infection
- swollen or itchy veins
- frequent infections such as 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. If your blood glucose levels are high you may feel lethargic or tired, have a headache and blurred vision, be thirsty and pass large amounts of urine.
- wounds not healing properly

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

- symptoms of an allergic reaction which may include: 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
- severe skin rash
Some types of severe skin rash may cause serious illness, and may be life-threatening. For example, severe skin reactions which start with painful red areas, then large blisters and ends with peeling of layers of skin. These may be accompanied by fever and chills, aching muscles and generally feeling unwell. Such rashes may be called 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 and vomiting, fast heart rate
- brown or dark coloured urine, with severe muscle aching and weakness (caused by muscle breakdown)
- sudden and severe headache or pain behind your eyes, sometimes with nausea and vomiting
- hearing problems, hearing loss, or ringing in your ears
- psychosis, including 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, including crying, changes in mood, trying to harm yourself, thoughts of suicide and attempting suicide
- 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.

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

Allergic reactions

If you think you are having an allergic reaction to isotretinoin, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, or other parts of the body
- rash, itching or hives on the skin
- fainting
- hayfever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay 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 they have passed their expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Isotretinoin looks like

- **10 mg capsules*:**
Red-orange, size 3, oval, soft gelatin capsules marked P10.
- **20 mg capsules*:**
Red-orange, size 6, oval, soft gelatin capsules marked P20.

Available in blister strips of 60 capsules.

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

Ingredients

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

It also contains the following inactive ingredients:

- 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 is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

- APO-Isotretinoin 10 mg capsule (blister pack):
AUST R 190940.
- APO-Isotretinoin 20 mg capsule (blister pack):
AUST R 190941.

Sponsor

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