

Terry White Chemists ISOTRETINOIN

contains the active ingredient, isotretinoin

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before taking your medicine. Ask your doctor or pharmacist if you do not understand anything or are worried about 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. Some more recent information may be available. Speak to your pharmacist or doctor to obtain the most up-to-date information.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking isotretinoin capsules against the benefits they expect it will have for you.

Keep this leaflet with the medicine.

You may need to read it again.

What isotretinoin is used for

Terry White Chemists Isotretinoin Capsules contain the active ingredient, isotretinoin.

Isotretinoin is used to treat acne.

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

How it works

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.

Your doctor, however, may have prescribed isotretinoin for another purpose.

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

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

Isotretinoin is not addictive.

Use in children

Do not give isotretinoin to children.

There is limited information on the safety of isotretinoin in children before puberty.

Before you take isotretinoin

When you must not take it

Do not take this medicine if:

- 1. You are pregnant, or for at least one month before you plan to fall pregnant**

Isotretinoin causes birth defects in humans if taken during pregnancy. If you fall pregnant while taking isotretinoin 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 breast-feeding**

Breast-feeding must stop before treatment begins. Do not breastfeed while taking isotretinoin.

- 3. you have had an allergic reaction to isotretinoin, Vitamin A, other retinoids, soya or any ingredients listed at the end of this leaflet.**

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; muscle pain or tenderness or joint pain or rash, itching or hives on the skin.

- 4. you are taking tetracycline antibiotics (such as Vibramycin®, Tetrex®, Doryx®, Achromycin®, Randomycin®, Minomycin®)**
- 5. you have kidney or 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, or the capsules do not look quite right**

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

- 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, contact your doctor.

Before you start to take it

You must tell your doctor if you:

- **have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes**
- **have any other health problems or issues including:**
 - diabetes, or a history of diabetes in your family
 - depression or a history of depression.
- **drink large amounts of alcohol.**

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

Taking other medicines

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

Some medicines may interfere with isotretinoin. These include:

- tetracycline antibiotics (such as Vibramycin, Achromycin, Tetrex, Doryx, Randomycin, Minomycin)
- vitamin A, or preparations containing vitamin A
- other medicines you are using to treat your acne

- other vitamins, herbal products, or medicines. Some of these medicines or nutritional supplements (e.g., St. John's wort) may make your birth control pills not work.
- the "mini-pill", a progestogen-only oral contraceptive pill

These medicines may be affected by isotretinoin, 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.

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

How to take isotretinoin

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

They may differ from the information contained in this leaflet.

If you do not understand any written instructions, ask your doctor or pharmacist for help.

Take isotretinoin exactly as your doctor has prescribed.

How much to take

Your doctor will tell you how many isotretinoin 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 therapy when the doctor knows how you respond to isotretinoin.

How to take it

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.

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.

When to take it

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

How long to take isotretinoin

Continue taking isotretinoin for as long as your doctor prescribes.

Acne treatment with isotretinoin 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 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 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.

If you forget to take isotretinoin

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 your medicine as you would normally.

Do not take an extra dose to make up for the dose that you missed by taking more than one dose at a time.

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

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, 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 you or anyone else may have taken too much isotretinoin.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Signs of overdose include transient headache (severe), nausea or vomiting, facial flushing, reddened lips, stomach pain, headache, drowsiness. Irritability, pruritus, dizziness and unsteady walking.

Keep telephone numbers for these places handy.

While you are taking isotretinoin

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 1 month after you finish taking isotretinoin.

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.

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 the 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 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.

Things you must not do

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

Do not use isotretinoin 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 with a pharmacist.

Do not donate blood during treatment with isotretinoin or for at least 4 weeks after stopping treatment.

Things to be careful of

During the first 3 weeks you are 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 1 to 2 months after 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 6 months. Your health care professional can help you choose the right skin products to reduce skin dryness and irritation.

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 2 weeks, check with your medical 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 behavior problems, including having thoughts about hurting themselves; check with your doctor right away if unusual mood or behavior 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.

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.

Be careful driving or operating machinery until you know how isotretinoin 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. 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 your vision is affected.

Wearing contact lenses during treatment with isotretinoin may cause discomfort.

Isotretinoin 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 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 2 or 3 weeks of treatment, and apply a sunscreen while taking isotretinoin.

Your skin may be more prone to sunburn while on isotretinoin. Use sunscreen or sunblocking lotions with a sun protection factor (SPF) of at least 15. Also, wear protective clothing and hats.

Avoid waxing and dermabrasion while taking isotretinoin and for 5 to 6 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.

Side Effects

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

Isotretinoin 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.

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 (scaling, redness, burning, pain or other signs of inflammation), mouth, nose, eyes 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
- back pain or joint pain
- bleeding or inflammation of gums
- peeling palms of the hands and soles of the feet
- tiredness

- headache
- feeling dizzy, drowsy or nervous
- an increased susceptibility to sunburn
- eye problems (burning, itching, redness, itching or other signs of eye inflammation)
- hair loss (sometimes occurs and is usually temporary but in rare cases, has persisted).

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 is lowered or stopped.

Stop taking isotretinoin and see your doctor if you experience any of the following:

- 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
- sudden numbness or weakness, especially on one side of the body
- tenderness or stiffness in your bones or joints, fracture
- blurred vision or visual disturbances, sudden and severe headache or pain behind your eyes, sometimes with vomiting

- hearing problems, hearing loss, or ringing in your ears
- loss of appetite, dark urine, clay-coloured stools, jaundice (yellowing of the skin or eyes), bleeding or bruising more easily than normal
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- psychosis, hallucinations (thinking, seeing or hearing things that are not real)
- aggression or agitation
- seizure, convulsions
- feeling unable to think and judge clearly
- sleep problems
- 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.

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.

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

After taking isotretinoin

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 degrees C.

Do not store isotretinoin, or any other medicine, in a bathroom or near a sink.

Do not leave it in the car or on window sills.

Protect isotretinoin from light and moisture.

Heat and dampness can destroy some medicines.

Keep isotretinoin 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 isotretinoin, or the capsules have passed their expiry date, ask your pharmacist what to do with any capsules that are left over.

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

Product Description

What it looks like

Terry White Chemists Isotretinoin 20 mg capsules are soft, oblong shaped, maroon in colour containing a yellow-orange opaque viscous liquid.

Terry White Chemists Isotretinoin capsules are available in blister strips of 60 tablets

Ingredients

Active Ingredient: isotretinoin

Terry White Chemists Isotretinoin 20 mg Each capsule contains 20 mg of isotretinoin.

Inactive Ingredients:

The capsules also contain:

- soya oil
- dl-alpha-tocopherol
- disodium edetate
- butylated hydroxyanisole
- partly hydrogenated soya oil
- yellow beeswax

- hydrogenated vegetable oil

The capsule shells contain:

- gelatin
- glycerol
- sorbitol
- titanium dioxide
- brilliant scarlet 4R
- purified water
- indigo carmine

Terry White Chemists Isotretinoin does not contain sucrose, gluten, tartrazine or any other azo dyes.

Australian Registration Number:

Terry White Chemists Isotretinoin 20 mg capsules AUST R 91350.

Sponsor

Apotex Pty Ltd

ABN 52 096 916 418

66 Waterloo Road

North Ryde, NSW 2113

Australia

Distributor

Symbion Pharmacy Services Pty Ltd

ABN 25 000 875 034

48-58 Overseas Drive

Noble Park North VIC 3174

Australia

Terry White Chemists is a registered trade mark of Symbion Pharmacy Services Pty Ltd.

This leaflet was updated in: December 2008.