Isotretinoin Gx

Consumer Medicine Information (CMI) Summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Isotretinoin Gx?

Isotretinoin Gx contains the active ingredient isotretinoin. Isotretinoin Gx is used to treat acne.

For more information, see Section 1. Why am I using Isotretinoin Gx? in the full CMI.

2. What should I know before I use Isotretinoin Gx?

Do not use if you have ever had an allergic reaction to Isotretinoin Gx or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section 2. What should I know before I use Isotretinoin Gx? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Isotretinoin Gx and affect how it works. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Isotretinoin Gx?

- Your doctor will tell you how many Isotretinoin Gx capsules to take each day, take them exactly as your doctor has prescribed.
- Isotretinoin Gx capsules should be swallowed whole with a glass of water or milk and must always be taken with food.

More instructions can be found in Section 4. How do I use Isotretinoin Gx? in the full CMI.

5. What should I know while using Isotretinoin Gx?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Isotretinoin Gx. • Use effective contraception for one month before, during and one month after treatment. • If you become pregnant while taking Isotretinoin Gx, stop taking it and tell your doctor immediately. • Tell your doctor if you are intending to do a lot of heavy lifting or exercise. • Your skin may be more sensitive while on Isotretinoin Gx. Avoid excessive sun exposure and certain skin and hair treatments.
Things you should not do	• Do not stop taking Isotretinoin Gx suddenly, change the dose or let yourself run out of medicine over the weekend or on holidays. • Do not give Isotretinoin Gx to anyone else even if their symptoms seem similar to yours. • Do not use Isotretinoin Gx to treat other complaints unless your doctor says to. • Do not donate blood during treatment with Isotretinoin Gx or for at least 1 month after stopping treatment.
Driving or using machines	• Be careful driving or operating machinery until you know how Isotretinoin Gx affects you.
Drinking alcohol	• You must tell your doctor if you drink large amounts of alcohol.
Looking after your medicine	• Keep the blister pack in a cool dry place where the temperature stays below 25°C. • Protect Isotretinoin Gx from light.

For more information, see Section 5. What should I know while using Isotretinoin Gx? in the full CMI.

6. Are there any side effects?

Isotretinoin Gx helps most people with acne but it may have unwanted side effects in a few people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects. When you are using Isotretinoin Gx, you can have some serious side effects. Serious side effects may include nausea, vomiting, persistent headache, blurred vision or visual disturbances, changes in your hearing or ringing in your ears, severe upper stomach pain, unexpected muscle pain, tenderness or weakness, blood in stools or severe diarrhoea, severe bruising, sudden red or itchy

spots, painful red areas, fever and chills, aching muscles, feeling depressed with or without suicidal thoughts and thinking, seeing or hearing things that are not real. For more information, including what to do if you have any side effects [Include statement of common side effects, and serious side effects, see Section 6. Are there any side effects? in the full CMI.

Isotretinoin Gx

Active ingredient(s): *isotretinoin*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Isotretinoin Gx. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Isotretinoin Gx.**

Where to find information in this leaflet:

1. Why am I using Isotretinoin Gx?
2. What should I know before I use Isotretinoin Gx?
3. What if I am taking other medicines?
4. How do I use Isotretinoin Gx?
5. What should I know while using Isotretinoin Gx?
6. Are there any side effects?
7. Product details

1. Why am I using Isotretinoin Gx?

Isotretinoin Gx contains the active ingredient isotretinoin.

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

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

Isotretinoin Gx is used to treat acne. There are many different types of medicines used to treat acne.

Isotretinoin Gx is used for more severe cases.

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

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

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

Isotretinoin Gx is not addictive.

2. What should I know before I use Isotretinoin Gx?

Warnings

Do not use Isotretinoin Gx if:

- you are allergic to isotretinoin, have had an allergic reaction to Isotretinoin Gx, vitamin A, other retinoids or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you are pregnant, or for at least one month before you plan to fall pregnant. If you fall pregnant while taking Isotretinoin Gx 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. You must stop breastfeeding before treatment begins. Do not breastfeed while taking Isotretinoin Gx.
- you are taking tetracycline antibiotics such as doxycycline
- you have severe liver disease
- you have very high fat levels (cholesterol, triglycerides) in your blood
- you have hypervitaminosis A. This is a condition caused by an excessive amount of vitamin A in the diet.
- the packaging is torn or shows signs of tampering
- 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 Gx, contact your doctor.

Do not give Isotretinoin Gx to children.

Isotretinoin Gx may be associated with slowing of growth when used in children before puberty. The use of Isotretinoin Gx in children less than 12 years of age is not recommended.

Check with your doctor if you:

- you drink large amounts of alcohol
- you have any allergies to any other medicines, foods, preservatives or dyes. Isotretinoin Gx capsules contain soya oil, which may contain traces of arachidic acid (a component of peanut oil).
- you have or have had any other health problems or issues including:
  - diabetes, or a history of diabetes in your family
  - depression (patients should have a mental health assessment before starting treatment)
  - liver disease
  - kidney disease
  - lipid (cholesterol or triglyceride) disorder
  - hormone disorder
  - eye disorders
  - stomach or bowel disease
  - difficulty getting or maintaining an erection (in males)
  - reduced sex drive or ability to feel pleasure
  - vaginal dryness (in females)
  - breast swelling in males

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and

how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

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

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

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

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

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

Some medicines may interfere with Isotretinoin Gx and affect how it works. These include:

- tetracycline antibiotics such as Doxycycline
- 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 Gx 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Isotretinoin Gx.

4. How do I use Isotretinoin Gx?

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 Gx exactly as your doctor has prescribed.
- Your doctor will tell you how many Isotretinoin Gx capsules to take each day.
- The dose will be calculated to suit your individual needs and your body weight. This dose may be adjusted during treatment when your doctor knows how you respond to Isotretinoin Gx.

When to take Isotretinoin Gx

- Isotretinoin Gx may be taken once or twice a day and 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 Gx treatment. This helps ensure that you aren't pregnant before you start taking Isotretinoin Gx.

How to take Isotretinoin Gx

- 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.

How long to take Isotretinoin Gx

- Continue taking Isotretinoin Gx for as long as your doctor prescribes.
- Acne treatment with Isotretinoin Gx will usually last 4 to 8 months. In the first few weeks of treatment your acne may get a little worse before it gets better. This is a sign that Isotretinoin Gx 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 Gx treatment is finished.
- Please note that Isotretinoin Gx 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 use Isotretinoin Gx

Isotretinoin Gx should be used regularly at the same time each day.

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

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

- This may increase the chance of getting an unwanted side effect.
- If you have missed several doses, please inform your doctor and follow the advice given to you.

If you take too much Isotretinoin Gx (overdose)

If you think that you have used too much Isotretinoin Gx, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**); or
- contact your doctor; or
- go to the Emergency Department at your nearest hospital.

You should 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.

5. What should I know while using Isotretinoin Gx?

Call your doctor straight away if you become pregnant while taking Isotretinoin Gx, stop taking it and tell your doctor immediately.

Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are using Isotretinoin Gx.
- 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 Gx 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 Gx.
- If you experience dryness of the lips, mouth, nose or skin, you can use a moisturiser or petroleum jelly to soften the areas not affected by the acne.
- Talk to your doctor if you experience persistent pain in your lower back or buttocks during treatment with Isotretinoin Gx. These symptoms may be signs of sacroiliitis, a type of inflammatory back pain. Your doctor may discontinue treatment with Isotretinoin Gx 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 should not do

- Do not stop taking Isotretinoin Gx suddenly 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 Gx to anyone else even if their symptoms seem similar to yours.
- Do not use Isotretinoin Gx to treat other complaints unless your doctor says to.
- Do not donate blood during treatment with Isotretinoin Gx or for at least 1 month after stopping treatment.

Things to be careful of

- Wearing contact lenses during treatment with Isotretinoin Gx may cause discomfort. Isotretinoin Gx 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 sunscreen whilst taking Isotretinoin Gx. Your skin may be more prone to sunburn while on Isotretinoin Gx.
- Avoid waxing and dermabrasion whilst taking Isotretinoin Gx and for 5 to 6 months after stopping Isotretinoin Gx treatment. Your skin may be more sensitive while on Isotretinoin Gx. Waxing may cause dermatitis and dermabrasion may cause scarring during and for several months after Isotretinoin Gx 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 Gx treatment.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Isotretinoin Gx affects you.

Normally Isotretinoin Gx 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 Gx. Make sure you know how you react to Isotretinoin Gx before you drive a car, operate machinery or do anything else that may be dangerous if your vision is affected.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- 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 as well.
- Store it in a cool dry place where the temperature stays below 25°C, away from moisture, heat or sunlight; for example, do not store it:
  - in the bathroom or near a sink, or
  - in the car or on window sills.

Keep Isotretinoin Gx where young children cannot reach it.

When to discard your medicine

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Symptoms associated with an excess of Vitamin A in the body (hypervitaminosis A): • dryness of the lips, mouth, nose and skin • peeling palms of the hands and soles of the feet • eye problems such as dry, sore, swollen or itchy eyes, discharge or trouble seeing at night • hoarseness • nosebleeds **Symptoms associated with skin and appendage disorders:** • fragile skin • change in colour of the skin • itchy skin rash • an increased susceptibility to sunburn • flaring of acne, usually at the start of treatment • sweating • changes to the nails • hair loss (sometimes occurs and is usually temporary but in rare cases has persisted) • excessive hairiness **Symptoms associated with musculoskeletal system disorders:** • tenderness or stiffness in your bones, joints or muscles • muscle or joint pain **Symptoms associated with the central nervous system:** • headache • tiredness **Symptoms associated with renal and urinary disorders:** • inflammation of the urethra **Symptoms associated with sexual and reproductive health:** • difficulty getting or maintaining an erection (in males)	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
• reduced sex drive or ability to feel pleasure • vaginal dryness (in females) • breast swelling in males	

Serious side effects

Serious side effects	What to do
Symptoms associated with skin and appendage disorders: • 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-centered marks. You may also have a fever, sore throat,headache and/ or diarrhoea. • painful red areas, that change to large blisters and end withpeeling 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. **Symptoms associated with the gastrointestinal system:** • nausea • vomiting • severe upper stomach pain • blood in stools or severe diarrhoea **Symptoms associated with the central nervous system**: • persistent headache **Symptoms associated with sensory disorders:** • blurred vision or visual disturbances • changes in your hearing or ringing in your ears • thinking, seeing or hearing things that are not real **Symptoms associated with musculoskeletal system disorders:** • unexpected muscle pain, tenderness or weakness • severe bruising • persistent pain in the lower back or buttocks **Symptoms associated with depression:** • feeling depressed, with or without suicidal thoughts • feeling sad or having crying spells	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
• 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 If symptoms of depression develop or worsen, speak with your doctor.	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with an authorised doctor's prescription.

What Isotretinoin Gx contains

Active ingredient (main ingredient)	isotretinoin
Other ingredients (inactive ingredients)	Capsule Filling • soya oil • yellow beeswax • partially hydrogenated soya oil • hydrogenated soya oil Capsule Shell • gelatin • glyceroll • titanium dioxide • ferrous oxide red and yellow
	Printing Ink • uses OPACODE monogramming ink S-1-17823 BLACK.

Do not take this medicine if you are allergic to any of these ingredients.

Isotretinoin Gx capsules come in two strengths, 10 mg and 20 mg.

Isotretinoin Gx 10 mg and 20 mg capsules are available in packs of 60 capsules.

What Isotretinoin Gx looks like

Isotretinoin Gx 10 mg – red-orange, size 3, oval, soft gelatin capsules marked P10. (AUST R 240732)

Isotretinoin Gx 20 mg – red-orange, size 6, oval, soft gelatin capsules marked P20. (AUST R 240733)

Who distributes Isotretinoin Gx

Sandoz Pty Ltd ABN 60 075 449 553
54 Waterloo Road
Macquarie Park, NSW 2113
Australia
Tel: 1800 726 369

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