APO-Isotretinoin

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 APO-Isotretinoin?

APO-Isotretinoin contains the active ingredient isotretinoin. APO-Isotretinoin is used to treat severe acne, where other treatments have not worked. For more information, see Section 1. Why am I using APO-Isotretinoin? in the full CMI.

2. What should I know before I use APO-Isotretinoin?

Do not use if you have ever had an allergic reaction to Isotretinoin 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 APO-Isotretinoin? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APO-isotretinoin 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 APO-Isotretinoin?

• Your doctor will tell you how many APO-Isotretinoin capsules to take each day, take them exactly as your doctor has prescribed.

• APO-Isotretinoin 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 APO-Isotretinoin? in the full CMI.

5. What should I know while using APO-Isotretinoin?

Things you should do	• Remind any doctor, dentist, or pharmacist you visit that you are using APO-Isotretinoin. • If you are about to start on any new medicine, tell your doctor and pharmacist that you are taking this medicine.
Things you should not do	• Do not stop taking APO-Isotretinoin suddenly, change the dose or let yourself run out of medicine over the weekend or on holidays. • 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 tell you to do. • Do not donate blood during treatment with APO-Isotretinoin or for at least 1 month after stopping treatment.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how APO-Isotretinoin 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.
Looking after your medicine	• 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 from light.

For more information, see Section 5. What should I know while using [insert medicine]? in the full CMI.

6. Are there any side effects?

APO-Isotretinoin 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. 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 diarrhea, 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, see Section 6. Are there any side effects? in the full CMI.

APO-Isotretinoin

Active ingredient(s): *Isotretinoin*

Consumer Medicine Information (CMI)

This leaflet provides important information about using APO-Isotretinoin. **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 APO-Isotretinoin.**

Where to find information in this leaflet:

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

1. Why am I using APO-Isotretinoin?

APO-Isotretinoin contains the active ingredient isotretinoin. APO-isotretinoin belongs to a group of medicines called retinoids, which are like Vitamin A.

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

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.

2. What should I know before I use APO-Isotretinoin?

Warnings

Do not use APO-Isotretinoin if:

- you are allergic to Isotretinoin, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- Do not take this medicine if you have an allergy to:
  - Isotretinoin
  - Vitamin A
  - Other retinoids
  - Soya
  - Any other 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.

Check with your doctor if you:

- **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
  - depression (patients should have a mental health assessment before starting treatment)
  - difficulty getting or maintaining an erection (in males)
  - reduced sex drive or ability to feel pleasure
  - vaginal dryness (in females)
  - breast swelling in males

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 pharmacists for disposal.

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

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

Check with your doctor if you are pregnant or intend to become pregnant.

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

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 breastmilk and your baby may be affected.

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.

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

Tell your doctor or pharmacist if you are taking any other medicine including that you get without your pharmacy 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 preparation containing vitamin A**
- **other acne treatments (e.g., strong creams, ointments, or gels)**
- **the 'mini-pill, a progesterone-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 pharmacists have more information on medicines to be careful with or avoid while taking this medicine.

Other medicine not listed above may also interact with isotretinoin.

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

4. How do I use APO-Isotretinoin?

How much to take / use

- **Follow all directions given to you by your doctor or pharmacists carefully.**
- They may be different to the information contained in the leaflet.
- **If you do not understand the instructions on the box, ask your doctor or pharmacist for help.**
- 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.
- **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 / use APO-Isotretinoin

- APO-Isotretinoin should be used 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 normal menstrual period before starting isotretinoin therapy.**
- This helps ensure that you aren't pregnant before you start taking isotretinoin.

How long to take APO-Isotretinoin

- **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 use APO-Isotretinoin

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

If you miss your dose at the usual time, take it as soon as you remember and then go back to taking your medicine as you would normally.

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 you experiencing side effects.

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

If you use too much APO-isotretinoin

If you think that you have used too much APO-Isotretinoin, 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.

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.

5. What should I know while using APO-Isotretinoin?

Things you should do

Call your doctor straight away if you:

- 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 start 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 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.**
- Tell your doctor if you feel APO-Isotretinoin are
- not helping your condition.
- Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.
- **Keep all your doctors' 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.
- **Tell your doctor if you experience persistent pain in your lower back or buttocks** during treatment with APO-Isotretinoin. These symptoms may be signs of sacroiliitis, a type of inflammatory back pain. Your doctor may discontinue treatment with APO-Isotretinoin 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 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 tell you to do.**
- **Do not stop taking you 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 diarrhea.
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. Moisturizer 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 behavior problems, including having thoughts about self-harm or suicide. Tell your doctor immediately if unusual mood or behavior 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 moisturizer 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

Driving or using machines

Be careful before you drive or use any machines or tools until you know how APO-Isotretinoin 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.

Looking after your medicine

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.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place 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.

Heat and dampness can destroy some medicines.

Keep it 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.

When to discard your medicine

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.

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
• 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 feet • Nail infection or inflammation • Dry throat or hoarse voice • Infection., 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 color. • Sexual dysfunction including impaired sexual function in males, decreased libido and gynaecomastia • An increased chance of sunburn • Initial worsening of acne • Hair loss (usually temporary but persisted in rare cases) • Changes in hair growth	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• Eye problem (burning, redness itching or other signs of eye inflammation or infections ; problem wearing contacts 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 diarrhea • 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.	**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.**

Very Serious Side Effects

Very Serious side effects	What to do
• 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	**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.**

Very Serious side effects	What to do
• 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 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 a doctor's prescription.

What APO-Isotretinoin contains

Active ingredient (main ingredient)	Isotretinoin
Other ingredients (inactive ingredients)	•soya oil •beeswax - yellow •soya oil - hydrogenated and partially hydrogenated •gelatin (phenylalanine & sulfites) •glycerol •titanium dioxide •iron oxide red •iron oxide yellow • OPACODE monogramming ink S-1-17823 BLACK •shellac
Potential allergens	**contains sulfites, phenylalanine and soybean products**

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

What APO-Isotretinoin 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.

Who distributes APO-Isotretinoin

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel Street

Cremorne VIC 3121

www.arrotex.com.au

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