

ERLYAND[®] Tablets

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.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using ERLYAND?

ERLYAND contains the active ingredient apalutamide. ERLYAND is used to treat patients with

- prostate cancer that has spread to other parts of the body and still responds to treatments that lower testosterone
- prostate cancer that has not spread to other parts of the body and no longer responds to a medical or surgical treatment that lowers testosterone.

For more information, see Section [1. Why am I using ERLYAND?](#) in the full CMI.

2. What should I know before I use ERLYAND?

Do not use if you have ever had an allergic reaction to ERLYAND 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 ERLYAND?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ERLYAND 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 ERLYAND?

- The recommended dose of ERLYAND is 240 mg (one 240 mg tablet or four 60 mg tablets) once a day.
- Swallow ERLYAND tablets whole with a glass of water. Do not break or chew them.

More instructions can be found in Section [4. How do I use ERLYAND?](#) in the full CMI.

5. What should I know while using ERLYAND?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist who are treating you that you are taking ERLYAND.• Use a reliable method of contraception (such as condoms) during treatment and for 3 months after your treatment with ERLYAND has finished.
Looking after your medicine	<ul style="list-style-type: none">• Store below 30°C. Keep the tablets in the original container.

For more information, see Section [5. What should I know while using ERLYAND?](#) in the full CMI.

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.

Common and less serious side effects are: feeling very tired, nausea, skin rash, weight loss, hot flushes, hypothyroidism, high blood pressure, decreased appetite, water retention, nausea, diarrhoea, joint pain, fractures and falls.

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.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

ERLYAND

Active ingredient(s): *apalutamide*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ERLYAND. **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 ERLYAND.**

Where to find information in this leaflet:

- [1. Why am I using ERLYAND?](#)
- [2. What should I know before ERLYAND?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ERLYAND?](#)
- [5. What should I know while using ERLYAND?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using ERLYAND?

ERLYAND contains the active ingredient apalutamide.

ERLYAND is an anticancer medicine and belongs to a group of medicines called androgen receptor inhibitors.

ERLYAND is used to treat patients with:

- **Prostate cancer that has not spread to other parts of the body and no longer responds to a medical or surgical treatment that lowers testosterone.**
- **Prostate cancer that has spread to other parts of the body and still responds to treatments that lower testosterone.**

2. What should I know before I use ERLYAND?

Warnings

Do not use ERLYAND if:

- you are allergic to apalutamide, 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 may be potentially pregnant. ERLYAND is not for use in women.

Check with your doctor if you:

- have a history of seizure, brain injury, stroke, or brain tumours (non-cancerous or cancerous) take any medicines for any other condition
- have a history of heart disease, high blood pressure, diabetes, have abnormal amounts of fat or cholesterol in your blood (dyslipidemia).

- have ever developed a severe rash over the body, usually with fever and swollen lymph nodes, and effects on blood cells and organs (drug reaction with eosinophilia and systemic symptoms or DRESS) or a severe skin rash or skin peeling, blistering and/or mouth sores (Stevens Johnson syndrome/toxic epidermal necrolysis).
- have a partner who is pregnant or may become pregnant. See additional information under Pregnancy and breastfeeding.

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

Do not father a child while taking ERLYAND and for 3 months after stopping treatment.

Use condoms and do not donate sperm during treatment and for 3 months after your treatment has finished. Talk with your healthcare providers if you have questions about birth control. If you plan to father a child, talk to your doctor or healthcare professional before taking ERLYAND. ERLYAND may harm your unborn baby.

Children and adolescents below 18 years of age

ERLYAND should not be used by anyone under 18 years of age because it has not been studied in this age group.

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.

Tell your doctor if you take any of the following medicines:

- warfarin, a medicine used to prevent blood clots
- omeprazole, a medicine used to treat heartburn or gastric and duodenal ulcers
- midazolam, often used as a sedative
- rosuvastatin or gemfibrozil, medicine used to lower your lipid levels
- fexofenadine, a medicine used to treat hay fever
- rifampin, a medicine used to treat certain infections
- antifungal medicines like itraconazole or ketoconazole.

ERLYAND might interact with other medicines. This may result in greater or lesser effects or even side effects from these medicines.

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

4. How do I use ERLYAND?

How much to take

- The recommended dose of ERLYAND is one 240 mg tablet or four 60 mg tablets once a day.

When to take ERLYAND

- Try to take ERYLAND at the same time each day. You may take them with or without food.

How to take ERLYAND

- Swallow ERLYAND tablets whole with a glass of water. Do not break or chew them.

If you have trouble swallowing the tablets whole:

For a 240 mg tablet, mix with one of the following non fizzy beverages or soft foods; orange juice, green tea, applesauce, or drinkable yogurt as follows:

- Place the whole ERLYAND 240 mg tablet in a cup. Do not crush or split the tablet.
- Add about 2 teaspoons (10 mL) of non fizzy water to make sure that the tablet is completely in water.
- Wait 2 minutes until the tablet is broken up and spread out, then stir the mixture.
- Add in 6 teaspoons or 2 tablespoons (30 mL) of one of the following non fizzy beverages or soft foods; orange juice, green tea, applesauce, or drinkable yogurt and stir the mixture.
- Swallow the mixture immediately.
- Rinse the cup with enough water to make sure the whole dose is taken and drink it immediately.
- Do not save the medicine/food mixture for later use.

For a 240 mg tablet, give through a feeding tube:

ERLYAND 240 mg tablet may also be given through certain feeding tubes. Ask your healthcare provider for specific instructions on how to properly take the tablet through a feeding tube.

For 60 mg tablets, mix with applesauce:

- Stir your entire dose of ERLYAND 60 mg tablets in 120 mL of applesauce. Do not crush the tablets.
- Stir after 15 minutes
- Stir again after 30 minutes until the tablets are well mixed with no chunks remaining.
- Using a spoon, swallow the mixture right away.
- Rinse the empty mixture container with 60 mL of water. Drink the water mixture and repeat the rinse with 60 mL of water one more time to make sure the medicine is swallowed completely. Drink the mixture within one hour of preparation. Do not store ERLYAND that is mixed with applesauce.

If you forget to use ERLYAND

ERLYAND should be used regularly at the same time each day. If you miss your dose at the usual time, take your normal dose as soon as possible on the same day. Return to your normal schedule on the following day.

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

If you use too much ERLYAND

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

You should immediately:

- phone the Poisons Information Centre (in Australia telephone **13 11 26**. In New Zealand telephone **0800 POISON** or **0800 764 766**), 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.

5. What should I know while using ERLYAND?

Things you should do

Be sure to keep all your doctor's appointments so your progress can be checked.

Be sure to follow your doctor's instructions about other medicines you should take, and other things you should do.

Remind any doctor, dentist or pharmacist who are treating you that you are taking ERLYAND.

Things you should not do

- Do not change your dose or stop taking ERLYAND unless your doctor tells you to.

Driving or using machines

There have been no studies on the effects of ERLYAND on the ability to drive or use machines. However, it is not anticipated that ERLYAND will affect the ability to drive and use machines.

Looking after your medicine

- Store below 30°C. Keep tablets in the original container.

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.

Keep it where young children cannot reach it.

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
<ul style="list-style-type: none"> feeling very tired nausea skin rash weight loss hot flushes hypothyroidism high blood pressure decreased appetite water retention nausea diarrhoea joint pain fractures and falls. 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Falls and fractures: ERLYAND treatment can cause bones and muscles to weaken and may increase your risk for falls and fractures. Falls and fractures have happened in people during treatment with ERLYAND. Falls were not caused by loss of consciousness (fainting) or seizures.</p>	<p>Your healthcare provider will monitor your risks for falls and fractures during treatment with ERLYAND.</p>
<p>Seizure: treatment with ERLYAND may increase your risk of having a seizure. You should avoid activities where a sudden loss of consciousness could cause serious harm to yourself or others.</p>	<p>Tell your healthcare provider right away if you have a loss of consciousness or seizure.</p>
<p>Heart disease, stroke, or mini-stroke: blockage of the arteries in the heart or in part of the brain (which can lead to death) has happened in some people during treatment with ERLYAND. If you get chest pain or discomfort (whether at rest or with activity) or shortness of breath, or if you get muscle weakness/paralysis in any part of the body, or difficulty in speaking during your treatment with ERLYAND.</p>	<p>Go to the nearest emergency department right away.</p>

Serious side effects	What to do
<p>Severe Cutaneous Adverse Reactions (SCAR): Severe rash with blisters and peeling skin, particularly around the mouth, nose, eyes, and genitals (Steven-Johnson syndrome)/Life threatening rash with blisters and peeling over much of the body (toxic epidermal necrolysis) and severe rash over the body, usually with fever and swollen lymph nodes, impacting blood cells and organs (drug reaction with eosinophilia and systemic symptoms)</p>	
<p>Interstitial lung disease: inflammation within the lungs that may lead to permanent damage.</p> <p>Restless leg syndrome: Uncomfortable feeling, with an irresistible urge to move your legs, and sometimes arms and other parts of your body.</p>	

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 ERLYAND contains

<p>Active ingredient (main ingredient)</p>	<p>Apalutamide 60 mg or 240 mg</p>
<p>Other ingredients (inactive ingredients)</p>	<p>ERLYAND 60 mg tablet</p> <p>Tablet Core:</p> <ul style="list-style-type: none"> croscarmellose sodium microcrystalline cellulose silicified microcrystalline cellulose colloidal anhydrous silica hypromellose acetate succinate magnesium stearate <p>Film-coat:</p>

	<ul style="list-style-type: none"> Opadry® II 85F210036 Green <p>ERLYAND 240 mg tablet</p> <p>Tablet Core:</p> <ul style="list-style-type: none"> Colloidal anhydrous silica Croscarmellose sodium Hypromellose acetate succinate Magnesium stearate Silicified microcrystalline cellulose <p>Film-coat</p> <ul style="list-style-type: none"> Iron oxide black glyceryl mono and dicaprylocaprate Polyvinyl alcohol Talc Titanium dioxide Macrogol poly(vinyl alcohol) grafted copolymer
Potential allergens	ERLYAND tablets are gluten- and lactose- free.

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

What ERLYAND looks like

ERLYAND 60 mg tablets are slightly yellowish to greyish green, oblong-shaped tablets with “AR 60” on one side. ERLYAND 60 mg tablets are supplied in bottles containing 120 tablets (AUST R 299792).

ERLYAND 240 mg tablets are bluish grey to grey, oval-shaped, film-coated tablets, debossed with “E240” on one side. ERLYAND 240 mg tablets are supplied in bottles containing 30 tablets (AUST R 408373).

Not all presentations may be available.

Who distributes ERLYAND

JANSSEN-CILAG Pty Ltd
 1-5 Khartoum Rd
 Macquarie Park
 NSW 2113 Australia
 Telephone: 1800 226 334

NZ Office: Auckland, New Zealand
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