

# ANDRIGA-5 and ANDRIGA-10 (ANDRIGA)

## 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 ANDRIGA?

ANDRIGA is a combination pack which contains two different medicines, abiraterone acetate 500mg film-coated tablets and prednisolone 5mg tablets. ANDRIGA is used to treat prostate cancer that has spread to other parts of the body.

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

### 2. What should I know before I use ANDRIGA?

Do not use if you have ever had an allergic reaction to abiraterone acetate, prednisolone 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 take ANDRIGA?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with ANDRIGA 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 ANDRIGA?

ANDRIGA should be used regularly each day. The dosage recommended by the doctor will depend on your condition. Do not take ANDRIGA with food.

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

### 5. What should I know while using ANDRIGA?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using ANDRIGA.</li><li>• Keep all of your doctor's appointments so that your condition can be monitored.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine suddenly.</li><li>• Do not give your medicine to anyone else, even if they have the same condition as you.</li><li>• Do not use more than the recommended daily dose.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how ANDRIGA affects you.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Tell your doctor if you drink alcohol.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store it in a cool dry place away from moisture, heat or sunlight.</li></ul>

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

### 6. Are there any side effects?

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some common side effects include diarrhoea, fluid retention in legs and feet, low blood potassium, urinary tract infection, high blood pressure and bone fractures. Other side effects include high fat levels in your blood, liver function test increases, indigestion, blood in urine, chest pain, heartbeat irregularities, heart failure, rapid heart rate, muscle pains, adrenal gland problems and anaphylactic reaction. Some side effects can only be detected when your doctor does tests to check your progress. So it is important to visit your doctor for regular check-ups.

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.

# ANDRIGA-5 and ANDRIGA-10 (ANDRIGA)

Active ingredients: *Abiraterone acetate and prednisolone*

## Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

## 1. Why am I using ANDRIGA?

ANDRIGA is a combination medicine pack which contains two different medicines, abiraterone acetate (a hormonal therapy drug) and prednisolone (a corticosteroid).

ANDRIGA is used to treat prostate cancer that has spread to other parts of the body.

The abiraterone acetate works by reducing the levels of male sex hormones in your body, including testosterone. The prednisolone must be taken to reduce the chance of developing high blood pressure, heart effects or low levels of potassium in your blood while you are taking abiraterone acetate.

## 2. What should I know before I use ANDRIGA?

### Warnings

**Do not use ANDRIGA if:**

- you are allergic to abiraterone acetate, prednisolone, 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 potentially be pregnant. ANDRIGA is not for use in women and children.
- you have severe liver failure. ANDRIGA should not be used in patients with severe liver failure. Ask your doctor if you have questions.
- you are being treated with XOFIGO. ANDRIGA and XOFIGO, a radiation therapy, should not be used together
- you have a current serious or uncontrolled infection, including fungal infections

- you have recently had any vaccinations

**Do not use ANDRIGA:**

- after the expiry date printed on the pack OR
- if the packaging is torn, doesn't look quite right or shows signs of tampering

If any of these apply, return the medicine to your pharmacist for disposal.

If you are not sure whether you should start using ANDRIGA, talk to your doctor.

**Check with your doctor if you:**

- have any other medical conditions, especially the following:
  - problems with your liver or kidneys
  - high blood pressure
  - heart problems
  - low levels of potassium in your blood
  - fluid retention (bloating, swollen legs, feet, ankles, puffiness in the abdomen, face and hips, sudden unexplained increase in weight)
  - hypoprothrombinaemia (a blood clotting disorder)
  - emotional problems or mental disorders
  - Cushing's disease (a hormone disorder)
  - seizures/epilepsy
  - a current serious or uncontrolled infection, including fungal infections
  - recent surgery or serious injury
  - stomach ulcers or other stomach or intestinal problems
  - osteoporosis (softening of the bone)
  - diabetes
  - tuberculosis
  - muscle weakness
  - glaucoma (high pressure in the eye) or cataracts
  - thyroid disease
- take any medicines for any other condition

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?](#)

### Problems with your liver

- You should not take ANDRIGA if you have moderate or severe liver disease. Your doctor will decide whether ANDRIGA can be used if you have a mild liver problem.
- ANDRIGA may affect your liver. When you are taking ANDRIGA your doctor will check your blood to look for any effects of ANDRIGA on your liver.

## High blood pressure and heart problems

- Abiraterone acetate (the violet-coloured film-coated tablets in the blister) can make high blood pressure or heart failure or low blood potassium worse. Taking prednisolone (the white tablets in the blister) with abiraterone helps to avoid worsening of these conditions. If you have these conditions, or other heart or blood vessel problems, discuss them with your doctor.

## Pregnancy and breastfeeding

ANDRIGA must not be taken by women who are pregnant or breast-feeding or might be pregnant since ANDRIGA may affect the baby.

If you are having sex with a pregnant woman you need to use a condom. If you are having sex with a woman who can become pregnant you need to use a condom and another effective birth control method.

If you are pregnant or might be pregnant, wear gloves if you need to touch or handle ANDRIGA.

## 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 and ANDRIGA may interfere with each other. These include:**

- medicines for bacterial infections (antibiotics) such as rifampicin and rifabutin
- cough medicines such as dextromethorphan
- medicines used to treat diabetes, such as pioglitazone or repaglinide
- medicines for epilepsy such as phenobarbital, phenytoin and carbamazepine
- some immunisations and vaccinations
- some medicines for heart disease, such as digoxin
- diuretics used to help kidneys get rid of salt and water from the body by increasing the amount of urine, such as spironolactone.
- XOFIGO (radium 223 dichloride) for treating prostate cancer
- medicines used to treat upset stomachs such as antacids
- potassium or salt supplements

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

## 4. How do I use ANDRIGA?

### How much to take

ANDRIGA contains two different medicines that need to be taken each day.

#### Abiraterone 500 mg film-coated tablets

- The usual daily dose is two 500 mg film-coated tablets taken as a single dose.

#### Prednisolone 5 mg tablets

- The usual dose is either one or two 5 mg tablets daily taken according to your doctor's instructions.

Follow the instructions provided and use ANDRIGA until your doctor tells you to stop.

## When to take ANDRIGA

DO NOT TAKE ANDRIGA WITH FOOD.

- ANDRIGA must be taken at least two hours after eating and food must not be eaten for at least one hour after taking the tablets.
- Swallow the tablets whole with water.

## If you forget to take ANDRIGA

ANDRIGA should be taken regularly each day.

If you miss a daily dose of the medicines contained within ANDRIGA, take your normal dose the following day. If more than one daily dose is missed, talk to your doctor.

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

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

## If you take too much ANDRIGA

If you think that you have taken too much ANDRIGA, 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.**

## 5. What should I know while taking ANDRIGA?

### Things you should do

**Keep all appointments with your doctor so that your progress can be checked.**

Your doctor will want to do some blood and other tests from time to time to check on your progress.

**Do not stop taking ANDRIGA unless your doctor tells you to do so.**

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

**Remind any doctor, dentist or pharmacist you visit that you are using ANDRIGA. If you are undergoing anaesthesia, tell your anaesthetist that you are taking ANDRIGA.**

**If you are about to be started on any new medicines, tell your doctor or pharmacist that you are taking ANDRIGA.**

### Call your doctor straight away if you:

- monitor your blood sugar while taking a medicine for diabetes and notice a drop in your blood sugar
- notice signs that your blood potassium may be low such as, muscle weakness, muscle twitching or heart palpitations

### Things you should not do

- Do not use stop taking this medicine suddenly.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not use more than the recommended daily dose.

### Driving or using machines

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

### Drinking alcohol

Tell your doctor if you drink alcohol.

### Looking after your medicine

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.

Keep it where young children cannot reach it.

### When to discard your medicine

Ask your pharmacist what to do with any ANDRIGA that is left over if:

- your doctor tells you to stop using ANDRIGA, or
- the expiry date has passed.

### 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.

Tell your doctor or pharmacist if you have any unpleasant effects while you are using ANDRIGA.

### Less serious side effects

Less serious side effects	What to do
<p><b>Stomach or gut related:</b></p> <ul style="list-style-type: none"><li>• diarrhoea or constipation</li><li>• indigestion</li><li>• nausea and vomiting</li><li>• increased appetite (which may result in weight gain)</li><li>• loss of appetite (which may result in weight loss)</li><li>• stomach bloating or irritation</li></ul> <p><b>Nervous system related:</b></p> <ul style="list-style-type: none"><li>• headache</li><li>• behavioural changes (mood swings, restlessness, anxiety or nervousness, trouble sleeping)</li></ul> <p><b>Skin related:</b></p> <ul style="list-style-type: none"><li>• changes to skin (acne, red or flushed face, bruising easily, red or purple streaks, thinning skin, extra hair growth, increased sweating, poor wound healing)</li></ul> <p><b>Infection related:</b></p> <ul style="list-style-type: none"><li>• urinary tract infection, which has symptoms such as frequent or painful urination, blood in urine, lower back or side pain</li><li>• an increased seriousness or frequency of infections</li></ul> <p><b>General body changes:</b></p> <ul style="list-style-type: none"><li>• bloating and rounding of the face (moon face)</li><li>• redistribution of body fat</li></ul>	<p><b>Speak to your doctor if you have any of these possible side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<p><b>Allergic reaction related:</b></p> <ul style="list-style-type: none"><li>• signs of an allergic reaction, such as difficulty swallowing or breathing; swelling of the face, lips, tongue or throat; or itchy rash</li></ul> <p><b>Heart and blood related:</b></p> <ul style="list-style-type: none"><li>• symptoms of heart problems, such as severe dizziness, fainting, weakness, chest pain, irregular heartbeat or rapid heart rate</li><li>• signs of heart failure, such as shortness of breath, fluid retention (swelling) in legs and feet</li><li>• signs of low blood potassium such as muscle weakness, muscle twitches and heart palpitations</li><li>• increases in liver function tests</li></ul>	<p><b>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</b></p>

<p><b>Bone related:</b></p> <ul style="list-style-type: none"> <li>bone fractures</li> </ul> <p><b>Kidney related:</b></p> <ul style="list-style-type: none"> <li>blood in urine</li> </ul> <p><b>Hormone system related:</b></p> <ul style="list-style-type: none"> <li>adrenal gland problems, which may confusion, extreme muscle weakness, dehydration, weight loss, low blood pressure</li> </ul> <p><b>Stomach or gut related:</b></p> <ul style="list-style-type: none"> <li>severe stomach or intestinal pain</li> </ul> <p><b>Nervous system related:</b></p> <ul style="list-style-type: none"> <li>epileptic fits</li> </ul> <p><b>Eye related:</b></p> <ul style="list-style-type: none"> <li>sudden changes in your vision</li> <li>decreased or blurred vision, cataracts</li> </ul> <p><b>Mood related:</b></p> <ul style="list-style-type: none"> <li>psychiatric (mental) disturbances</li> </ul>	
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Some side effects can only be detected when your doctor does tests to check your progress. So it is important to visit your doctor for regular check-ups. Such side effects may include:

- osteoporosis or other changes in bone which can result in an increased chance of fractures due to brittleness or softening of the bone
- changes in other hormone levels in your body
- changes in the body's ability to handle glucose (steroid diabetes)
- effects on the parathyroid and thyroid glands which control calcium and body metabolism
- increased amounts of cholesterol in the blood
- changes to your white blood cells
- changes to your nervous system which may affect the way your nerves work
- changed sperm count
- increased blood pressure
- slow heart rate
- increased pressure in the skull

**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](http://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 ANDRIGA contains

#### Abiraterone acetate 500 mg film-coated tablets:

<b>Active ingredient (main ingredient)</b>	Abiraterone acetate
<b>Other ingredients (inactive ingredients)</b>	Lactose monohydrate Croscarmellose sodium Hypromellose Sodium lauryl sulfate Magnesium stearate Microcrystalline cellulose Colloidal anhydrous silica Macrogol poly (vinyl alcohol) grafted copolymer Purified talc Titanium dioxide Iron oxide red Iron oxide black
<b>Potential allergens</b>	Contains lactose

#### Prednisolone 5 mg tablets:

<b>Active ingredient (main ingredient)</b>	Prednisolone
<b>Other ingredients (inactive ingredients)</b>	Lactose monohydrate Potato starch Gelatin Purified talc Magnesium stearate
<b>Potential allergens</b>	Contains lactose

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

### What ANDRIGA looks like

ANDRIGA contains two different medicines:

#### Abiraterone acetate 500 mg film-coated tablets:

Violet, oval-shaped, film-coated tablets, debossed with "500" on one side and plain on the other side.

#### Prednisolone 5 mg tablets:

White, round, tablets with a score line on one side of the tablet.

ANDRIGA is available in blister packs in the following pack sizes:

#### ANDRIGA-5:

4 blisters containing a total of 56 abiraterone 500 mg film-coated tablets and 28 prednisolone 5 mg tablets (AUST R 437512).

8 blisters containing a total of 112 abiraterone 500 mg film-coated tablets and 56 prednisolone 5 mg tablets (AUST R 437512).

**ANDRIGA-10:**

4 blisters containing a total of 56 abiraterone 500 mg film-coated tablets and 56 prednisolone 5 mg tablets (AUST R 437511).

8 blisters containing a total of 112 abiraterone 500 mg film-coated tablets and 112 prednisolone 5 mg tablets (AUST R 437511).

**Who distributes ANDRIGA**

Actor Pharmaceuticals Pty Ltd  
Level 6, 50 Berry Street  
North Sydney, NSW, 2060  
Australia  
Telephone: 1800 322 690  
[www.actorpharma.com.au](http://www.actorpharma.com.au)

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