

XTANDI®

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 XTANDI?

XTANDI contains the active ingredient enzalutamide. XTANDI is used to treat adult men with prostate cancer that no longer responds to hormone therapy or surgical treatment to lower testosterone, or has spread to other parts of the body and is considered "hormone sensitive".

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

2. What should I know before I use XTANDI?

Do not use if you have ever had an allergic reaction to XTANDI 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. XTANDI is not for use in women.

For more information, see Section [2. What should I know before I use XTANDI?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with XTANDI 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 XTANDI?

- The usual dose is four 40 mg capsules taken at the same time once a day. Your doctor may reduce your dose depending on your medical conditions.

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

5. What should I know while using XTANDI?

| | |
|---------------------------------|--|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using XTANDI. |
| Things you should not do | <ul style="list-style-type: none">• Do not take XTANDI to treat any other complaints unless your doctor tells you to. |

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|---|--|
| <p>Things you should do</p> | <ul style="list-style-type: none"> ● Remind any doctor, dentist or pharmacist you visit that you are using XTANDI. |
| | <ul style="list-style-type: none"> ● Do not give your medicine to anyone else, even if they have the same condition as you. ● Do not stop taking your medicine or alter the dosage without checking with your doctor. |
| <p>Driving or using machines</p> | <ul style="list-style-type: none"> ● Do not drive or operate machinery until you know how XTANDI affects you. ● XTANDI may have a moderate effect on your ability to drive or use any tools or machinery as the side effects for XTANDI includes seizures. |
| <p>Looking after your medicine</p> | <ul style="list-style-type: none"> ● Keep your capsules in the pack until it is time to take them. ● Keep your capsules in the original packaging in a cool dry place where |

| | |
|-----------------------------|--|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using XTANDI. |
| | the temperature stays below 25°C. |

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

6. Are there any side effects?

There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur (see the full CMI for more details). The most common and serious side effects are breathlessness, chest pain, fall, broken bones, cancer as a result of previous treatment with radiation or chemotherapy.

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.

XTANDI® (ex-TAN-dee)

Active ingredient(s): *enzalutamide* (enza-LOOT-ah-mide)

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using XTANDI?

XTANDI contains the active ingredient enzalutamide. XTANDI is an androgen receptor inhibitor.

XTANDI is used to treat adult men with prostate cancer that no longer responds to hormone therapy or surgical treatment to lower testosterone, or has

spread to other parts of the body and is considered "hormone sensitive".

This medicine works by blocking the activity of hormones called androgens (such as testosterone). By blocking androgens, XTANDI stops prostate cancer cells from growing and dividing.

2. What should I know before I use XTANDI?

Warnings

Do not use XTANDI if:

- you are allergic to enzalutamide, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- XTANDI is not for use in women.

Check with your doctor if you:

have any other medical conditions such as:

- a history of seizures
- a serious head injury or a history of head trauma
- a stroke
- a brain tumour, or cancer which has spread to the brain
- drink very large amounts of alcohol either regularly or from time to time

- are taking a medicine that can cause seizures or that increases risks for having seizures (see Section [3. What if I am taking other medicines?](#)).

(In some of these situations you may have a higher risk of having a seizure.)

take any medicines for any other condition such as:

- heart or blood pressure problems
- kidney problems
- a partner who is pregnant or is planning to become pregnant.

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.

This medicine may cause harm to the unborn child or potential loss of pregnancy if it is taken by women who are pregnant. It must not be taken by women who are pregnant, may become pregnant, or who are breast feeding.

This medicine could possibly have an effect on male fertility.

If you are having sex with a woman who can become pregnant, you must use a condom and another effective birth control method, during treatment and for 3 months after stopping treatment with this medicine. Men who are sexually active with a pregnant woman must use a condom during and for 3 months after stopping treatment with XTANDI to protect the unborn child.

Female caregivers see Section [4. How do I use XTANDI?](#) for handling and use.

Talk with your doctor if you have questions about birth control. Your doctor can discuss with you the risks and benefits involved.

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

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.

When taken at the same time as XTANDI, these medicines may increase the risk of a seizure:

- certain medicines used to treat asthma and other respiratory diseases (e.g. aminophylline, theophylline)
- medicines used to treat certain psychiatric disorders such as depression and schizophrenia (e.g. clozapine, olanzapine, risperidone, ziprasidone, bupropion,

lithium, chlorpromazine, thioridazine, amitriptyline, desipramine, doxepin, imipramine, mirtazapine)

- certain medicines for the treatment of pain (e.g. pethidine).

Some medicines and XTANDI may interfere with each other. These include certain medicines used to:

- treat pain (e.g. fentanyl, tramadol, paracetamol)
- thin the blood, or to prevent blood clots (e.g. warfarin, clopidogrel)
- lower cholesterol (e.g. gemfibrozil, atorvastatin, simvastatin)
- treat cancer (e.g. cabazitaxel)
- treat epilepsy (e.g. carbamazepine, clonazepam, phenytoin, primidone, valproic acid)
- treat certain psychiatric disorders such as severe anxiety or schizophrenia (e.g. diazepam, midazolam, haloperidol)
- treat sleep disorders (e.g. zolpidem)
- treat heart conditions or lower blood pressure (e.g. bisoprolol, digoxin, diltiazem, felodipine, nicardipine, nifedipine, propanolol, verapamil)
- treat serious disease related to inflammation (e.g. dexamethasone, prednisolone)
- lower your immunity (e.g. cyclosporin, tacrolimus)
- treat HIV infection (e.g. indinavir, ritonavir)
- treat bacterial infections (e.g. clarithromycin, doxycycline, rifampicin)
- treat thyroid disorders (e.g. levothyroxine)
- treat gout (e.g. colchicine)

- prevent heart conditions or strokes (dabigatran etexilate)
- treat reflux disease or peptic ulcers (e.g. omeprazole).

These medicines may be affected by XTANDI 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 pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Some medicines may interfere with XTANDI and affect how it works.

Medicines that may increase the effect of XTANDI include:

- gemfibrozil
- itraconazole

Medicines that may reduce the effect of XTANDI include:

- rifampicin

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

4. How do I use XTANDI?

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 the instructions on the box, ask your doctor or pharmacist for help.

How much to take

- The usual dose is four 40 mg capsules taken at the same time once a day. Your doctor may reduce your dose depending on your medical conditions.
- Reduced dose:
If you are taking a reduced dose of XTANDI, you may use the remaining capsules in the open dose compartment for your next scheduled dose, provided that the capsules have been otherwise stored under the conditions described below (see [Looking after your medicine](#)).
- Follow the instructions provided and use XTANDI until your doctor tells you to stop.

How to take it

- Swallow the capsules whole with a full glass of water. Do not chew, dissolve or open the capsules before swallowing.
- You can take XTANDI with or without food.
- XTANDI should not be handled by persons other than the patient and his caregivers. Women who are or may become pregnant should not handle damaged or opened enzalutamide capsules without protection, e.g., gloves.

When to take XTANDI

- XTANDI should be taken at about the same time each day. Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

If you forget to use XTANDI

XTANDI 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 you forget to take XTANDI for the whole day, take your usual dose the following day.

If you forget to take XTANDI for more than one day, talk to your doctor immediately.

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 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.

If you use too much XTANDI

If you think that you have used too much XTANDI, 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.

You may be at increased risk of experiencing a seizure.

5. What should I know while using XTANDI?

Things you should do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking XTANDI.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

Keep all of your doctor's appointments so that your progress can be checked.

Call your doctor straight away if:

- your partner becomes pregnant while taking this medicine.

Remind any doctor, dentist or pharmacist you visit that you are using XTANDI.

Things you should not do

- Do not take XTANDI to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not stop taking your medicine or alter the dosage without checking with your doctor.

Driving or using machines

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

XTANDI may have a moderate influence on your ability to drive or use any tools or machinery. Seizures have been reported in patients taking XTANDI. If you are at higher risk of seizures, talk to your doctor.

Looking after your medicine

- Keep your capsules in the pack until it is time to take them.
- If you take the capsules out of the pack they may not keep as well.

- If you are taking a reduced dose of XTANDI, you may store the remaining capsules in the open dose compartment until the next dose, provided that the capsules have been otherwise stored under the conditions described below.
- Keep your capsules in the original packaging in a cool dry place where the temperature stays below 25°C.
- Do not take any capsule that is leaking, damaged, or shows signs of tampering.
- A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

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

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 that is left over.

Do not throw away any medicines via wastewater or household waste.

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?

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

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.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Less serious side effects

| Less serious side effects | What to do |
|---|--|
| <ul style="list-style-type: none">• headache• weakness• tiredness• dizziness | 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 |
|--|-------------------|
| <ul style="list-style-type: none"> ● breathlessness ● chest pain ● swelling of the hands, ankles or feet ● rash ● pain in back, muscles or joints ● hot flushes ● falls ● broken bones ● hallucinations ● feeling anxious ● dry skin ● itching ● high blood pressure ● constipation ● diarrhoea ● feeling sick ● decreased appetite ● difficulty remembering things ● difficulty thinking clearly ● forgetfulness ● reduced concentration ● cancer as a result of previous treatment | |

| Less serious side effects | What to do |
|---|-------------------|
| <p>with radiation or chemotherapy</p> <ul style="list-style-type: none"> ● change in sense of taste ● difficulty swallowing this medicine | |

Serious side effects

| Serious side effects | What to do |
|--|--|
| <ul style="list-style-type: none"> ● Seizures Seizures were reported in 5 in every 1,000 people taking XTANDI and in fewer than 3 in every 1,000 people taking placebo. Seizures are more likely if you take more than the recommended dose of this medicine, if you take certain other medicines, or if you are at higher risk of seizure. If you have a seizure, see your doctor as soon as possible or go to Accident and Emergency at your nearest hospital | <p>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.</p> |

| Serious side effects | What to do |
|--|-------------------|
| <p>immediately. Your doctor may decide that you should stop taking XTANDI.</p> <ul style="list-style-type: none"> ● Posterior Reversible Encephalopathy Syndrome (PRES) - There have been rare reports of PRES (may affect up to 1 in 1,000 people), a rare, reversible condition involving the brain, in patients treated with XTANDI. If you have a seizure, worsening headache, confusion, blindness or other vision problems, please contact your doctor as soon as possible. ● Choking There have been reports of choking due to product size. Swallow the capsules whole with a full glass of water. | |

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 XTANDI contains

| | |
|---|--|
| Active ingredient (main ingredient) | enzalutamide |
| Other ingredients (inactive ingredients) | caprylocaproyl macrogolglycerides butylated hydroxyanisole |

| | |
|--|---|
| | butylated hydroxytoluene gelatin sorbitol sorbitan solution glycerol titanium dioxide purified water OPACODE WB monogramming ink NSP-78-17827 BLACK |
|--|---|

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

What XTANDI looks like

XTANDI capsules are white to off-white, oblong soft gelatin capsules with "ENZ" written on one side in black ink.

XTANDI is available in packs of 112 capsules (in 4 wallets of 28 capsules each).

(AUST R 210494)

Who distributes XTANDI

XTANDI is distributed in Australia by:

Astellas Pharma Australia Pty Ltd

Suite 2.01, 2 Banfield Road

Macquarie Park, NSW 2113

Medical Information:

1800 751 755

® = Registered Trademark

This leaflet was prepared in August 2024.