Xtandi® Soft Capsules

Consumer Medication Information Leaflet (RiMUP)

Enzalutamide (40mg)

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1. What *Xtandi*® is used for

Xtandi® contains the active substance enzalutamide. *Xtandi*® is used to treat adult men with prostate cancer:
- That no longer responds to a hormone therapy or surgical treatment to lower testosterone.

Or
- That has spread to other parts of the body and responds to a hormone therapy or surgical treatment to lower testosterone.

Or
- Who had prior prostate removal or radiation and have rapidly rising PSA, but cancer has not spread to other parts of the body and responds to a hormone therapy to lower testosterone.

2. How *Xtandi*® works

Xtandi® is a medicine that works by blocking the activity of hormones called androgens (such as testosterone). By blocking androgens, enzalutamide stops prostate cancer cells from growing and dividing.

3. Before you use *Xtandi*®

When you must not use it
- If you are allergic to enzalutamide or any of the other ingredients of this medicine listed in section '*Ingredients'*
- If you are pregnant or may become pregnant (see '*Pregnancy, breast-feeding and fertility'*)

Before you start use it

Warnings and precautions

Seizure

Seizures were reported in 6 in every 1,000 people taking *Xtandi*®, and fewer than 3 in every 1,000 people taking placebo (see '*Taking other medicines*' in this section and section '*Side effects*').

If you are taking a medicine that can cause seizures or that can increase the susceptibility for having seizures (see '*Taking other medicines*').

If you have a seizure during treatment: See your doctor as soon as possible. Your doctor may decide that you should stop taking *Xtandi*®.

Posterior Reversible Encephalopathy Syndrome (PRES)

There have been rare reports of PRES, 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. (See also section '*Side effects*').

Risk of new cancers (second primary malignancies)

There have been reports of new (second) cancers including cancer of the bladder and colon in patients treated with *Xtandi*®.
See your doctor as soon as possible if you notice signs of gastrointestinal bleeding, blood in the urine, or frequently feel an urgent need to urinate when taking *Xtandi*®.

Difficulty swallowing related to capsule formulation

There have been reports of patients experiencing difficulty swallowing this medicine, including choking. Difficulty swallowing or choking was reported more frequently in patients taking the capsule formulation, which may be related to its larger capsule size. Swallow the capsules whole with a sufficient amount of water.

If you have difficulties swallowing large capsules or a history of dysphagia, you may have difficulties swallowing *Xtandi*® capsules, or be at risk of choking. *Xtandi*® tablets may be a suitable alternative. Ask your doctor for further advice.

Talk to your doctor before taking *Xtandi*®:
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking *Xtandi*® or other medicines
- If you are taking any medicines to prevent blood clots (e.g. warfarin, acenocoumarol, clopidogrel)
- If you use chemotherapy like docetaxel
- If you have problems with your liver
- If you have problems with your kidneys

Please tell your doctor if you have any of the following:
Any heart or blood vessel conditions, including heart rhythm problems (arrhythmia), or are being treated with medicines for these conditions. The risk of heart rhythm problems may be increased when using *Xtandi*®.

If you are allergic to enzalutamide, this may result in a rash or swelling of the face, tongue, lip or throat. If you are allergic to enzalutamide or any of the other ingredients of this medicine, do not take *Xtandi*®.

Serious skin rash or skin peeling, blistering and/or mouth sores, including Stevens-Johnson syndrome, have been reported in association with *Xtandi*® treatment. Stop using *Xtandi*® and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section '*Side effects*'.

If any of the above applies to you or you are not sure, talk to your doctor before taking this medicine.

Children and adolescents

This medicine is not for use in children and adolescents.

Pregnancy, breast-feeding and fertility

***Xtandi*® is not for use in women**. This medicine may cause harm to the unborn child 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, use a condom and another effective birth control method, during treatment and for 3 months after treatment with this medicine. If you are having sex with a pregnant woman, use a condom to protect the unborn child.
Female caregivers see section 'Taking *Xtandi*®' for handling and use.

Xtandi® contains sorbitol
This medicine contains 57.8 mg sorbitol (a type of sugar) per soft capsule.

Taking other medicines
Tell your doctor if you are taking, have recently taken or might take any other medicines. You need to know the names of the medicines you take. Keep a list of them with you to show to your doctor when you are prescribed a new medicine. You should not start or stop taking any medicine before you talk with the doctor that prescribed *Xtandi*®.
Tell your doctor if you are taking any of the following medicines. 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, mesoridazine, thioridazine, amitriptyline, desipramine, doxepin, imipramine, maprotiline, mirtazapine)
- Certain medicines for the treatment of pain (e.g. pethidine)

Tell your doctor if you are taking the following medicines. These medicines may influence the effect of *Xtandi*®, or *Xtandi*® may influence the effect of these medicines:

This includes certain medicines used to:
- Lower cholesterol (e.g. gemfibrozil, atorvastatin, simvastatin)
- Treat pain (e.g. fentanyl, tramadol)
- 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, propranolol, verapamil)
- Treat serious disease related to inflammation (e.g. dexamethasone, prednisolone)
- Treat HIV infection (e.g. indinavir, ritonavir)
- Treat bacterial infections (e.g. clarithromycin, doxycycline)
- Treat thyroid disorders (e.g. levothyroxine)
- Treat gout (e.g. colchicine)
- Treat stomach disorders (e.g. omeprazole)
- Prevent heart conditions or strokes (e.g. dabigatran etexilate)
- Prevent organ rejection (e.g. tacrolimus)

Xtandi® might interfere with some medicines used to treat heart rhythm problems (e.g. quinidine, procainamide, amiodarone and sotalol) or might increase the risk of heart rhythm problems when used with some other drugs [e.g. methadone (used for pain relief and part of drug addiction detoxification), moxifloxacin (an antibiotic), antipsychotics (used for serious mental illnesses)].

Tell your doctor if you are taking any of the medicines listed above. The dose of *Xtandi*® or any other medicines that you are taking may need to be changed.

4. How to use *Xtandi*®
How much to use
The usual dose is 160 mg (four capsules), taken at the same time once a day.

When to use it
Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Taking *Xtandi*®
- Swallow the soft capsules whole with a sufficient amount of water.
- Do not chew, dissolve or open the soft capsules before swallowing.
- *Xtandi*® can be taken with or without food.
- *Xtandi*® should not be handled by persons other than the patient or his caregivers. Women who are or may become pregnant should not handle damaged or opened *Xtandi*® capsules without wearing protection like gloves.

Your doctor may also prescribe other medicines while you are taking *Xtandi*®.

How long to use it
Continue taking *Xtandi*® for as long as your doctor recommends.

If you forget to use it
- If you forget to take *Xtandi*® at the usual time, take your usual dose as soon as you remember.
- 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.
- Do not take a double dose to make up for the dose you forgot.

If you use too much (overdose)
If you take more soft capsules than prescribed, stop taking *Xtandi*® and contact your doctor. You may have an increased risk of seizure or other side effects.

If you have difficulties swallowing large capsules or have a history of dysphagia *Xtandi*® capsules are not recommended for patients who have difficulty swallowing large capsules or who have dysphagia. *Xtandi*® tablets are recommended as an alternative.

If you have difficulties swallowing large capsules or have a history of dysphagia, you may experience difficulty

swallowing *Xtandi*® capsules or be at risk of choking. *Xtandi*® tablets may be used as an alternative. Ask your doctor for further advice.

5. While you are using it

Things you must do

Take your medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Things you must not do

Do not stop taking the medicine unless your doctor tells you to.

Do not take any new medicines without consulting your doctor.

Do not give *Xtandi*® to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

Driving and using machines

Xtandi® may have moderate influence on the ability to drive and use machines. Seizures have been reported in patients taking *Xtandi*®.

If you are at higher risk of seizures, talk to your doctor.

Fertility

This medicine could possibly have an effect on male fertility.

6. Side effects

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

Seizures were reported in 6 in every 1,000 people taking *Xtandi*®, and 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 than usual risk of seizure.

If you have a seizure, see your doctor as soon as possible. Your doctor may decide that you should stop taking *Xtandi*®.

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.

Other possible side effects include:

Very common (may affect more than 1 in 10 people)

- Tiredness, falls, broken bones, hot flushes, high blood pressure

Common (may affect up to 1 in 10 people)

- Headache, feeling anxious, dry skin, itching, difficulty remembering, blockage of the arteries in the heart (ischemic heart disease), breast enlargement in men (gynaecomastia), nipple pain, breast tenderness, symptom of restless legs syndrome (an uncontrollable urge to move a part of the body, usually the leg), reduced concentration, forgetfulness, change in sense of taste, difficulty thinking clearly

Uncommon (may affect up to 1 in 100 people**)**

- Hallucinations, low white blood cell count, increased liver enzyme levels in blood test (a sign of liver problems)

Not known (frequency cannot be estimated from the available data)

- Muscle pain, muscle spasms, muscular weakness, back pain, difficulty swallowing this medicine including choking, upset stomach including feeling sick (nausea), a skin reaction that causes red spots or patches on the skin that may look like a target or "bulls-eye" with a dark red centre surrounded by paler red rings (erythema multiforme), or another serious skin reaction presenting reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes that can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome), rash, being sick (vomiting), swelling of the face, lips, tongue and/or throat, diarrhoea, decreased appetite

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my
[Consumers -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

7. Storage and Disposal of *Xtandi*®

Storage

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the outer carton after EXP. The expiry date refers to the last day of that month.

Store below 30°C.

Do not take any soft capsule that is leaking, damaged, or shows signs of tampering.

Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

8. Product Description

What it looks like

Xtandi® soft capsules are white to off-white, oblong soft capsules (approximately 20 mm by 9 mm) with "ENZ" written on one side.

Ingredients

- Active ingredient: Enzalutamide

- Inactive ingredients:
  - The other ingredients of the capsule are caprylocaproyl macrogol-8

glycerides, butylhydroxyanisole (E320), and butylhydroxytoluene (E321).
- The ingredients of the capsule shell are gelatin, sorbitol sorbitan solution, glycerol, titanium dioxide (E171), and purified water.
- The ingredients of the ink are iron oxide black (E172) and polyvinyl acetate phthalate.

MAL number(s):
MAL16045039ACRZ

9. Manufacturer
Catalent Pharma Solutions, LLC
2725 Scherer Drive
St. Petersburg, FL 33716, USA

Product Registration Holder
Astellas Pharma Malaysia Sdn. Bhd.
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