Package leaflet: Information for the patient

Enzalutamide Clonmel 160 mg film-coated tablets
enzalutamide

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Enzalutamide Clonmel is and what it is used for
2. What you need to know before you take Enzalutamide Clonmel
3. How to take Enzalutamide Clonmel
4. Possible side effects
5. How to store Enzalutamide Clonmel
6. Contents of the pack and other information

1. What Enzalutamide Clonmel is and what it is used for

Enzalutamide Clonmel contains the active substance enzalutamide. Enzalutamide Clonmel 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.

How Enzalutamide Clonmel works
Enzalutamide Clonmel 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.

2. What you need to know before you take Enzalutamide Clonmel

Do not take Enzalutamide Clonmel
- If you are allergic to enzalutamide or any of the other ingredients of this medicine (listed in section 6)
- If you are pregnant or may become pregnant (see 'Pregnancy, breast-feeding and fertility')

Warnings and precautions
Seizures
Seizures were reported in 6 in every 1,000 people taking Enzalutamide Clonmel, and fewer than 3 in every 1,000 people taking placebo (see 'Other medicines and Enzalutamide Clonmel' below and section 4 'Possible side effects').

If you are taking a medicine that can cause seizures or that can increase the susceptibility for having seizures (see 'Other medicines and Enzalutamide Clonmel' below).

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

Posterior reversible encephalopathy syndrome (PRES)
There have been rare reports of PRES, a rare, reversible condition involving the brain, in patients treated with Enzalutamide Clonmel. If you have a seizure, worsening headache, confusion, blindness or other vision problems, please contact your doctor as soon as possible. (See also section 4 'Possible 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 Enzalutamide Clonmel.

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 Enzalutamide Clonmel.

Difficulty swallowing related to product formulation
There have been reports of patients experiencing difficulty swallowing Enzalutamide tablets, including reports of choking. Swallow the tablets whole with a sufficient amount of water.

Talk to your doctor before taking Enzalutamide Clonmel
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Enzalutamide Clonmel 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 Enzalutamide Clonmel.

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 Enzalutamide Clonmel.

Serious skin rash or skin peeling, blistering and/or mouth sores, including Stevens-Johnson syndrome, have been reported in association with Enzalutamide Clonmel treatment. Stop using Enzalutamide Clonmel and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

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.

Other medicines and Enzalutamide Clonmel
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 Enzalutamide Clonmel.

Tell your doctor if you are taking any of the following medicines. When taken at the same time as Enzalutamide Clonmel, 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 Enzalutamide Clonmel, or Enzalutamide Clonmel 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)

Enzalutamide Clonmel 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 medicines [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 Enzalutamide Clonmel or any other medicines that you are taking may need to be changed.

Pregnancy, breast-feeding and fertility
- **Enzalutamide Clonmel is not for use in women.** This medicine may cause harm to the unborn child or potential loss of pregnancy if 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, during treatment and for 3 months after treatment with this medicine.
- Female caregivers see section 3 'How to take Enzalutamide Clonmel' for handling and use.

Driving and using machines
Enzalutamide Clonmel may have moderate influence on the ability to drive and use machines. Seizures have been reported in patients taking Enzalutamide Clonmel. If you are at higher risk of seizures, talk to your doctor.

Enzalutamide Clonmel contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

3. How to take Enzalutamide Clonmel

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

The usual dose is 160 mg (one 160 mg film-coated tablet), taken at the same time once a day.

Taking Enzalutamide Clonmel
- Swallow the tablets whole with a sufficient amount of water.
- Do not cut, crush or chew the tablets before swallowing.
- Enzalutamide Clonmel can be taken with or without food.
- Enzalutamide Clonmel should not be handled by persons other than the patient or his caregivers. Women who are or may become pregnant should not handle broken or damaged Enzalutamide Clonmel tablets without wearing protection like gloves.

Your doctor may also prescribe other medicines while you are taking Enzalutamide Clonmel.

If you take more Enzalutamide Clonmel than you should
If you take more tablets than prescribed, stop taking Enzalutamide Clonmel and contact your doctor. You may have an increased risk of seizure or other side effects.

If you forget to take Enzalutamide Clonmel
- If you forget to take Enzalutamide Clonmel at the usual time, take your usual dose as soon as you remember.
- If you forget to take Enzalutamide Clonmel for the whole day, take your usual dose the following day.
- If you forget to take Enzalutamide Clonmel for more than one day, talk to your doctor immediately.
- **Do not take a double dose** to make up for a forgotten dose.

If you stop taking Enzalutamide Clonmel
Do not stop taking this medicine unless your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

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

Seizures

Seizures were reported in 6 in every 1,000 people taking Enzalutamide Clonmel, 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 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 Enzalutamide Clonmel.

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 Enzalutamide Clonmel. 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, fall, 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, changes in ECG (QT prolongation), 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, reduction in blood platelets (which increases risk of bleeding or bruising), diarrhoea, decreased appetite

Reporting of side effects
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:
Ireland: HPRA Pharmacovigilance, Website: www.hpra.ie
Malta: ADR Reporting, Website: www.medicinesauthority.gov.mt/adrportal
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Enzalutamide Clonmel

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 and blister or bottle label after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not remove oxygen absorbing canister from bottles.

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.

6. Contents of the pack and other information

What Enzalutamide Clonmel contains

- The active substance is enzalutamide.
- Each film-coated tablet contains 160 mg of enzalutamide.

The other ingredients are:

- Tablet core: Methacrylic acid-ethyl acrylate copolymer (1:1) Type A (contains Sodium Lauryl sulfate and Polysorbate 80), colloidal anhydrous silica (E551), microcrystalline cellulose PH 102 (E460), croscarmellose sodium (E468), magnesium stearate (E470b).
- Tablet coating: Hypromellose 2910 (E464), macrogol 3350 (E1521), titanium dioxide (E171), iron oxide yellow (E172), talc (E553b).

What Enzalutamide Clonmel looks like and contents of the pack

Enzalutamide Clonmel 160 mg film-coated tablets are yellow, oval, film-coated tablets (tablets), debossed with “160” on one side, with dimensions 23 mm x 11 mm.

Each pack of Enzalutamide Clonmel contains 28, 56 film-coated tablets in Aluminium-OPA/Alu/PVC blisters, or 28 x 1, 56 x 1 film-coated tablets in Aluminium-OPA/Alu/PVC perforated unit dose blisters.
Enzalutamide Clonmel is also supplied in multipacks of 84 (2 packs of 42) film-coated tablets in Aluminium-OPA/Alu/PVC blisters, or multipacks of 84 x 1 (2 packs of 42 x 1) film-coated tablets in Aluminium-OPA/Alu/PVC perforated unit dose blisters.
Enzalutamide Clonmel is also supplied in high density polyethylene (HDPE) bottles with white polypropylene (PP) oxygen absorbing canister, closed with a child resistant polypropylene (PP) closure, containing 28 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer
PharOS MT Ltd, HF62X, Hal Far Industrial Estate, Birzebbugia BBG3000, Malta
Pharos Pharmaceutical Oriented Services Ltd, Lesvou Street End, Thesi Loggos Industrial Zone, Metamorfossi, 14452, Greece
STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

This medicine is authorised in the Member States of the European Economic Area under the following names:
Netherlands: Enzalutamide CF 160 mg, filmomhulde tabletten

Belgium:	Enzalutamide EG 160 mg filmomhulde tabletten
Germany:	Enzalutamid STADA 160 mg Filmtabletten
Hungary:	Enzalutamide STADA 160 mg filmtabletta
Ireland:	Enzalutamide Clonmel 160 mg film-coated tablets
Luxembourg:	Enzalutamide EG 160 mg comprimés pelliculés
Malta:	Enzalutamide Clonmel 160 mg film-coated tablets
Poland:	Enzalutamide STADA
Portugal:	Enzalutamida Stada
Romania:	Enzalutamidă Stada 160 mg comprimate filmate
Slovakia:	Enzalutamide STADA 160 mg
Slovenia:	Enzalutamid STADA 160 mg filmsko obložene tablete
Spain:	Enzalutamida STADA 160 mg comprimidos recubiertos con película

This leaflet was last revised in September 2025.