

Package leaflet: Information for the patient

Enzalutamide Accord 40 mg soft capsules 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 Accord is and what it is used for
2. What you need to know before you take Enzalutamide Accord
3. How to take Enzalutamide Accord
4. Possible side effects
5. How to store Enzalutamide Accord
6. Contents of the pack and other information

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

Enzalutamide Accord contains the active substance enzalutamide. Enzalutamide Accord is used to treat adult men with prostate cancer that:

- No longer responds to a hormone therapy or surgical treatment to lower testosterone
- Or
- 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 Accord works

Enzalutamide Accord 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 Accord

Do not take Enzalutamide Accord

- 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, and fewer than 3 in every 1,000 people taking placebo (See 'Other medicines and Enzalutamide Accord' 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 Accord’ 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 Accord.

Posterior reversible encephalopathy syndrome (PRES)

There have been rare reports of PRES, a rare, reversible condition involving the brain, in patients treated with enzalutamide. 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 Accord.

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 Accord.

Difficulty swallowing related to product formulation

There have been reports of patients experiencing difficulty swallowing this medicine, including reports of choking. The swallowing difficulties or choking events were more commonly observed in patients receiving capsules, which could be related to a larger product size. Swallow the capsules whole with a sufficient amount of water.

If you have difficulties swallowing large capsules or a history of dysphagia, you can have difficulties swallowing Enzalutamide Accord capsules, or a risk of choking. An alternative could be taking Enzalutamide Accord tablets, ask your doctor.

Talk to your doctor before taking Enzalutamide Accord

- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Enzalutamide Accord 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 Accord.

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 Accord.

Serious skin rash or skin peeling, blistering and/or mouth sores, including Stevens-Johnson syndrome, have been reported in association with Enzalutamide Accord treatment. Stop using Enzalutamide Accord 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 Accord

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 Accord.

Tell your doctor if you are taking any of the following medicines. When taken at the same time as Enzalutamide Accord, 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 Accord, or Enzalutamide Accord 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 Accord 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 Accord or any other medicines that you are taking may need to be changed.

Pregnancy, breast-feeding and fertility

- **Enzalutamide Accord 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.

- Female caregivers see section 3 'How to take Enzalutamide Accord' for handling and use.

Driving and using machines

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

Enzalutamide Accord contains sorbitol

This medicine contains 47.80 mg sorbitol (E 420) in each soft capsule.

3. How to take Enzalutamide Accord

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 (four soft capsules), taken at the same time once a day.

Taking Enzalutamide Accord

- Swallow the soft capsules whole with a sufficient amount of water.
- Do not chew, dissolve or open the soft capsules before swallowing.
- Enzalutamide Accord can be taken with or without food.
- Enzalutamide Accord 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 Enzalutamide Accord capsules without wearing protection like gloves.

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

If you take more Enzalutamide Accord than you should

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

If you forget to take Enzalutamide Accord

- If you forget to take Enzalutamide Accord at the usual time, take your usual dose as soon as you remember.
- If you forget to take Enzalutamide Accord for the whole day, take your usual dose the following day.
- If you forget to take Enzalutamide Accord 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 stop taking Enzalutamide Accord

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

If you have difficulties swallowing large capsules or a history of dysphagia

Enzalutamide capsules should not be given to patients who have difficulties swallowing large capsules, or patients with dysphagia. It is recommended that enzalutamide tablets are used instead.

If you have difficulties swallowing large capsules or a history of dysphagia, you can have difficulties swallowing Enzalutamide Accord capsules, or a risk of choking. An alternative could be taking Enzalutamide Accord tablets, ask your doctor.

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

Commented [A01]: This statement is missing.

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, 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 Accord.

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. 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:

HPRA Pharmacovigilance;

Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Enzalutamide Accord

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

This medicine does not require any special storage conditions.

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

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 Accord contains

- The active substance is enzalutamide. Each soft capsule contains 40 mg of enzalutamide.
- The other ingredients of the soft capsule are caprylocaproyl macroglycerides, butylhydroxyanisole (E 320), and butylhydroxytoluene (E 321).
- The ingredients of the soft capsule shell are gelatin, sorbitol liquid partially dehydrated (E 420), glycerol, titanium dioxide (E 171), talc (E 553b) and purified water.
- The ingredients of the ink are shellac, iron oxide black, ammonium hydroxide and propylene glycol.

What Enzalutamide Accord looks like and contents of the pack

- Enzalutamide Accord soft capsules are white to off-white colour, opaque, oblong shape (20 mm in length and 10 mm in width) soft capsule and imprinted "JG1" in black ink.
 - Enzalutamide Accord is available in PVC/PCTFE-Alu blister packs containing 28 soft capsules in a carton. Enzalutamide Accord is also available in multipacks that comprise 4 cartons, each containing 28 soft capsules.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Accord Healthcare Ireland Limited
Euro House
Euro Business Park
Little Island
Cork T45 K857
Ireland

Manufacturer

Accord Healthcare Polska Sp.z o.o.,
ul. Lutomierska 50,
95-200 Pabianice,
Poland

Accord Healthcare B.V.
Winthontlaan 200,
3526 KV Utrecht, Netherland

Pharmadox Healthcare Limited

KW20A Kordin Industrial Park, Paola PLA
3000, Malta

Accord Healthcare single member S.A.
64th Km National Road Athens,
Lamia, Schimatari,
32009, Greece

This medicine is authorised in the Member States of the European Economic Area under the following names:

Name of the member state	Name of the medicine
Austria	Enzalutamid Accord 40 mg Weichkapseln
Belgium	Enzalutamide Accord 40 mg zachte capsules/capsule molle/ Weichkapseln
Germany	Enzalutamide Accord 40 mg Weichkapseln
Estonia	Enzalutamide Accord
Latvia	Enzalutamide Accord 40 mg mīkstās kapsulas
Lithuania	Enzalutamide Accord 40 mg minkštosios kapsulės
Czech Republic	Enzalutamide Accord
Croatia	Enzalutamid Accord 40 mg meke kapsule
Hungary	Enzalutamide Accord 40 mg lágy kapszula
Poland	Enzalutamide Accord
Romania	Enzalutamidă Accord 40 mg capsule moi
France	Enzalutamide Accord 40 mg, capsule molle
Cyprus	Enzalutamide Accord 40 mg Καψάκιο, μαλακό
Greece	ENZALUTAMIDE/ACCORD
Spain	Enzalutamida Accord 40 mg cápsulas blandas EFG
Italy	Enzalutamide Accord
Ireland	Enzalutamide Accord 40 mg soft capsules

This leaflet was last revised in September 2025.