

## **PACKAGE LEAFLET**

### **Package leaflet: Information for the patient**

**Enzalutamide Rowex 40 mg film-coated tablets**  
**Enzalutamide Rowex 80 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 Rowex is and what it is used for
2. What you need to know before you take Enzalutamide Rowex
3. How to take Enzalutamide Rowex
4. Possible side effects
5. How to store Enzalutamide Rowex
6. Contents of the pack and other information

#### **1. What Enzalutamide Rowex is and what it is used for**

Enzalutamide Rowex contains the active substance enzalutamide. Enzalutamide Rowex 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.

#### **How Enzalutamide Rowex works**

Enzalutamide Rowex 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 Rowex**

##### **Do not take Enzalutamide Rowex**

- 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 5 in every 1,000 people taking Enzalutamide Rowex, and fewer than one in every 1,000 people taking placebo (see 'Other medicines and Enzalutamide Rowex' 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 Rowex' 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 Rowex.

### Posterior reversible encephalopathy syndrome (PRES)

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

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 Rowex.

### **Talk to your doctor before taking Enzalutamide Rowex**

- 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 Rowex.

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 Rowex.

Severe skin rash or skin peeling, blistering and/or mouth sores have been reported in association with Enzalutamide Rowex treatment. Seek medical attention immediately if you notice any of these symptoms.

**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 Rowex**

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 Rowex.

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

#### **Pregnancy, breast-feeding and fertility**

- **Enzalutamide Rowex 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 Rowex' for handling and use.

#### **Driving and using machines**

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

#### **Enzalutamide Rowex contains lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

#### **Enzalutamide Rowex contains sodium**

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

### **3. How to take Enzalutamide Rowex**

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 40 mg film-coated tablets or two 80 mg film-coated tablets), taken at the same time once a day.

#### **Taking Enzalutamide Rowex**

- Swallow the tablets whole with water.
- Do not cut, crush or chew the tablets before swallowing.
- Enzalutamide Rowex can be taken with or without food.
- Enzalutamide Rowex 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 Rowex tablets without wearing protection like gloves.

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

#### **If you take more Enzalutamide Rowex than you should**

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

**If you forget to take Enzalutamide Rowex**

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

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 5 in every 1,000 people taking Enzalutamide Rowex, and in fewer than one 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 Rowex.

**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 Rowex. 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), 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.

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

Hallucinations, difficulty thinking clearly, low white blood cell count.

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

Muscle pain, muscle spasms, muscular weakness, back pain, changes in ECG (QT prolongation), upset stomach including feeling sick (nausea), 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.

### **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 the national reporting system: HPRA

Pharmacovigilance; website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects, you can help provide more information on the safety of this medicine.

## **5. How to store Enzalutamide Rowex**

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, cardboard wallet, blister and bottle after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Rowex contains**

- The active substance is enzalutamide.  
Enzalutamide Rowex 40 mg film-coated tablets: Each film-coated tablet contains 40 mg of enzalutamide.  
Enzalutamide Rowex 80 mg film-coated tablets: Each film-coated tablet contains 80 mg of enzalutamide.
- The other ingredients are:
  - Tablet core: Hypromellose acetate succinate, lactose monohydrate, croscarmellose sodium (E468), microcrystalline cellulose (E460) and magnesium stearate (E470b)
  - Tablet coating: Hypromellose, (E464), macrogol, talc, titanium oxide (E171) and iron oxide yellow (E172).

### **What Enzalutamide Rowex looks like and contents of the pack**

Enzalutamide Rowex 40 mg film-coated tablets are yellow, round, biconvex film-coated tablets debossed with “EN” on one side and “40” on the other side; diameter 10.5 – 11.3 mm.

Enzalutamide Rowex 80 mg film-coated tablets are yellow, oval, biconvex film-coated tablets debossed with “EN” on one side and “80” on the other side; length 16.9 – 17.7 mm; width 8.9 – 9.7 mm.

This medicine is packed in PVC/PVDC//Aluminium blisters or a HDPE bottle with desiccant, closed with child-resistant polypropylene screw cap with induction heat seal liner.

Enzalutamide Rowex 40 mg film-coated tablets is presented in a carton box containing 28 or 112 film-coated tablets (in blister or blister incorporated in a cardboard wallet), 28x1 or 112x1 film-coated tablets (in perforated unit-dose blister) or 112 film-coated tablets (in a bottle).

Enzalutamide Rowex 80 mg film-coated tablets} is presented in a carton box containing 14 or 56 film-coated tablets (in blister or blister incorporated in a cardboard wallet), 14x1 or 56x1 film-coated tablets (in perforated unit-dose blister) or 56 film-coated tablets (in a bottle).

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturers**

#### **Marketing Authorisation Holder**

Rowex Ltd., Bantry, Co. Cork, Ireland.

#### **Manufacturers**

Lek Pharmaceuticals d.d., Verovškova Ulica 57, Ljubljana 1526, Slovenia.

Lek Pharmaceuticals d.d., Trimlini 2D, Lendava 9220, Slovenia.

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

Austria	Enzalutamid Sandoz 40 mg - Filmtabletten Enzalutamid Sandoz 80 mg - Filmtabletten
Bulgaria	Enzalutamide Sandoz 40 mg filmcoated tablets Ензалутамид Сандоз 40 mg филмирани таблетки
Croatia	Enzalutamid Sandoz 40 mg filmom obložene tablete Enzalutamid Sandoz 80 mg filmom obložene tablete
Cyprus	Enzalutamide/Sandoz
Czechia	Enzalutamide Sandoz
Denmark	Enzalutamide Sandoz
Estonia	Enzalutamide Sandoz
Finland	Enzalutamide Sandoz 40 mg tabletti kalvopäällysteinen Enzalutamide Sandoz 80 mg tabletti kalvopäällysteinen
France	ENZALUTAMIDE SANDOZ 40 mg, comprimé pelliculé ENZALUTAMIDE SANDOZ 80 mg, comprimé pelliculé
Germany	Enzalutamid HEXAL 40 mg Filmtabletten Enzalutamid HEXAL 80 mg Filmtabletten
Greece	Enzalutamide/Sandoz
Hungary	Enzalutamid Sandoz 40 mg filmtabletta Enzalutamid Sandoz 80 mg filmtabletta
Iceland	Enzalutamide Sandoz
Ireland	Enzalutamide Rowex 40 mg film-coated tablets Enzalutamide Rowex 80 mg film-coated tablets
Italy	Enzalutamide Sandoz
Latvia	Enzalutamide Sandoz 40 mg apvalkotās tablets

Lithuania	Enzalutamide Sandoz 80 mg apvalkotās tabletes
	Enzalutamide Sandoz 40 mg plēvele dengtos tabletēs
Malta	Enzalutamide Sandoz 80 mg plēvele dengtos tabletēs
	Enzalutamide Sandoz 40 mg film coated tablets
Netherlands	Enzalutamide Sandoz 80 mg film coated tablets
	Enzalutamide Sandoz 40 mg, filmomhulde tabletten
Norway	Enzalutamide Sandoz 40 mg, filmomhulde tabletten
	Enzalutamide Sandoz
Poland	Enzalutamid Sandoz
Romania	Enzalutamidă Sandoz 40 mg, comprimate filmate
	Enzalutamidă Sandoz 80 mg, comprimate filmate
Slovakia	Enzalutamid Sandoz 40 mg filmom obalené tablety
	Enzalutamid Sandoz 80 mg filmom obalené tablety
Slovenia	Enzalutamid Sandoz 40 mg filmsko obložene tablete
	Enzalutamid Sandoz 80 mg filmsko obložene tablete
Spain	Enzalutamida Sandoz 40 mg comprimidos recubiertos con película EFG
	Enzalutamida Sandoz 80 mg comprimidos recubiertos con película EFG
Sweden	Enzalutamide Sandoz

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