

ENCASTRY® ENZALUTAMIDE

ENCASTRY® (ENZALUTAMIDE) SOFT GELATIN CAPSULE FOR ORAL USE

Read this patient information carefully before you start taking Encastry® because it answers some common questions about Encastry®. This medication is prescribed for your current condition, therefore do not use it in similar cases and do not recommend it to others. To report SUSPECTED ADVERSE REACTIONS, contact Noavaran Daroui Kimia Co. at +982166433514 or send email to medical@kimia-pharma.co

Read this patient information carefully before you start taking Encastry® because it contains important information for you. This leaflet does not take the place of talking with your healthcare provider about your medical condition or treatment.

Composition

Each liquid filled soft gelatin capsule Encastry® 40 mg contains 40 mg of Enzalutamide.

Mechanism of action

Enzalutamide is an androgen receptor inhibitor.

Pharmacokinetic

Absorption

The median T_{max} is 1 hour (0.5 to 3 hours) following a single 160 mg dose of capsules.

Distribution

The mean (%CV) volume of distribution after a single oral dose is 110 L (29%). Encastry® is 97% to 98% bound to plasma proteins.

Metabolism

Encastry® is metabolized by CYP2C8 and CYP3A4.

Elimination

Encastry® is primarily eliminated by hepatic metabolism. Following oral administration of ¹⁴C-enzalutamide, 71.0% is recovered in urine and 13.6% is in faeces.

Indication

Encastry® is indicated for the treatment of patients with:

- Castration-resistant prostate cancer (CRPC)
- Metastatic castration-sensitive prostate cancer (mCSPC)

The safety and efficacy of Encastry® have not been established in females and pediatric patients.

Dosage and Administration

- The recommended dosage of Encastry® is 160 mg administered orally once daily with or without food.
- Patients receiving Encastry® should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy.

Side effects / Adverse reactions

It should be noted that these side effects do not occur in all patients. These are not all the possible side effects of Encastry®. For more information, ask your healthcare provider or pharmacist.

Encastry® may cause serious side effects including:

- **Seizure.** If you take Encastry® you may be at risk of having a seizure. Discuss conditions that may predispose to seizures and medications that may lower the seizure threshold. You should avoid activities where a sudden loss of consciousness could cause serious harm to yourself or others. Tell your healthcare provider right away if you have loss of consciousness or seizure.
- **Posterior Reversible Encephalopathy Syndrome (PRES).** If you take Encastry® you may be at risk of developing a condition involving the brain called PRES. Tell your healthcare provider right away if you have a seizure or quickly worsening symptoms such as headache, decreased alertness, confusion, reduced eyesight, blurred vision or other visual problems. Your healthcare provider will do a test to check for PRES.
- **Allergic Reactions.** Allergic reactions have happened in people who take Encastry®. Stop taking Encastry® and get medical help right away if you develop swelling of the face, tongue, lip or throat.
- **Heart disease.** Blockage of the arteries in the heart (ischemic heart disease) that can be life threatening has happened in some people during treatment with Encastry®. Your healthcare provider will monitor you for signs and symptoms of heart problems during your treatment with Encastry®. Call your healthcare provider or go to the nearest emergency room right away if you get chest pain or discomfort at rest or with activity or shortness of breath during your treatment with Encastry®.
- **Falls and fractures.** Encastry® treatment may increase your risk for falls and fractures. Falls were not caused by loss of consciousness (fainting) or seizures. Your healthcare provider will monitor your risks for falls and fractures during treatment with Encastry®.

Your healthcare provider will stop treatment with Encastry® if you have serious side effects.

Call your healthcare provider right away if you have any of aforementioned symptoms.

The most common side effects

The most common side effects in people who take Encastry® include:

- Weakness or feeling more tired than usual
- Back pain
- Hot flashes
- Constipation
- Joint pain
- Decreased appetite
- Diarrhea
- High blood pressure

Drug Interaction

- **Strong CYP2C8 inhibitors:** Co-administration of Encastry® with strong CYP2C8 inhibitors (gemfibrozil) should be avoided, if possible, as they can increase the plasma exposure to Encastry®. If co-administration cannot be avoided, the dose of Encastry® should be reduced.

- **Strong CYP3A4 inducers:** Co-administration of Encastry® with rifampin (a strong CYP3A4 inducer and a moderate of CYP2C8 inducer) should be avoided if possible due to decreases plasma concentrations and efficacy of Encastry®. If co-administration of a strong CYP3A4 inducer with Encastry® cannot be avoided, the dose of Encastry® should be increased.
- **CYP3A4, CYP2C9 and CYP2C19 substrates:** The co-administration of Encastry® decreases the concentrations of certain CYP3A4, CYP2C9, or CYP2C19 substrates, which may reduce the efficacy of these substrates. Avoid the co-administration of Encastry® with certain CYP3A4, CYP2C9, or CYP2C19 substrates for which a minimal decrease in concentration may lead to therapeutic failure of the substrate. If the co-administration cannot be avoided, increase the dosage of these substrates in accordance with their Prescribing Information.

Warnings

Before taking Encastry®, tell your healthcare provider about all your medical conditions, including if you:

- have a history of seizures, brain injury, stroke, or brain tumors.
- have a history of heart disease.
- have high blood pressure.
- have abnormal amounts of fat or cholesterol in your blood (dyslipidemia).
- are pregnant or plan to become pregnant. Encastry® can cause harm to your unborn baby and loss of pregnancy (miscarriage).
- have a partner who is pregnant or is able to become pregnant.
- are breastfeeding or plan to breastfeed.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Encastry® and other medicines may affect each other causing side effects.

You should not start or stop any medicine before you talk with the healthcare provider that prescribed Encastry®. Know the medicines you take. Keep a list of them with you to show your healthcare provider and pharmacist when you get a new medicine.

Missed dose

If you miss a dose of Encastry®, take your prescribed dose as soon as you remember that day. If you miss your daily dose, take your prescribed dose at your regular time the next day. Do not take more than your prescribed dose of Encastry® each day.

Overdose

If you take too much Encastry®, call your healthcare provider or go to the nearest emergency room right away. You may have an increased risk of seizure if you take too much Encastry®.

Pregnancy and lactation

Avoid taking Encastry® if you are breastfeeding, pregnant or plan to become pregnant. Women who are or may become pregnant should not handle damaged or opened Encastry® capsules without wearing protection like gloves.

Encastry® can cause harm to your unborn baby and loss of pregnancy (miscarriage). If you are pregnant or plan to become pregnant, or if you have a partner who is pregnant or may become pregnant, tell your healthcare provider right away.

Male patients with female partners of reproductive potential or pregnant females must use condoms in combination with an effective contraception during treatment with Encastry® and for 3 months after the last dose of Encastry®. Encastry® may cause fertility problems in male patients.

It is not known if Encastry® passes into your breast milk. If you are breastfeeding or plan to breastfeed tell your healthcare provider. You and your healthcare provider should decide if you will take Encastry® or breastfeed. Avoid doing both.

Patient information

- Take Encastry® exactly as your healthcare provider tells you.
- Take your prescribed dose of Encastry® once daily, at the same time each day.
- Your healthcare provider may change your dose if needed.
- Do not change or stop taking your prescribed dose of Encastry® without talking with your healthcare provider first.
- Encastry® can be taken with or without food.
- Swallow Encastry® capsules whole. Do not chew, dissolve, or open the capsules.
- If you are receiving gonadotropin-releasing hormone (GnRH) therapy, you should continue with this treatment during your treatment with Encastry® unless you have had a surgery to lower the amount of testosterone in your body (surgical castration).

Storage

- Keep away from light and moisture. Store below 30°C.
- Keep Encastry® capsules dry and in the original container.
- Keep out of the reach of children.
- Safely throw away medicine that is out of date or that you no longer need.

Packaging

- Boxes of 6 alu/alu blisters of 5 soft capsules. Each pack contains 4 boxes of 30 soft capsules.

License Holder:

Noavaran Daroui Kimia Co., Tehran, Iran.

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www.kimia-pharma.co

References

https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/203415s018,213674s0051bl.pdf

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https://www.ema.europa.eu/en/documents/product-information/xstandi-epar-product-information_en.pdf