

ENZANEAL™ 40

Enzalutamide Capsules 40 mg

Presentation: Each hard gelatin capsule contains:

Enzalutamide..... 40 mg

Excipients..... q.s.

Approved colours used in empty capsule shell.

Pharmaceutical form: Hard Gelatin Capsules

Indications: For the treatment adults with metastatic castration-resistant prostate cancer (mCRPC) whose disease has progressed on or after Docetaxel therapy.

Dosage and administration: The recommended dose is 160 mg of **enzalutamide** (two 40 mg capsules) as a single oral daily dose.

Method of administration: For oral administration only. The capsules should be swallowed whole without opening and are not to be chewed or dissolved or opened.

Contraindications: • Individual hypersensitivity to the active substance or excipients of the product. • **Enzalutamide** is not indicated for use by women who are or may become pregnant.

Warnings & precautions: Seizure Risk: **Enzalutamide**, an antiandrogen, carries a risk of seizures. Cardiovascular Risk: New hormonal agents for mCRPC treatment may increase cardiovascular toxicity. QT Interval Prolongation: Androgen deprivation therapy, including **enzalutamide**, may prolong QT intervals. Hypersensitivity Reactions: Hypersensitivity reactions, including tongue, lip, and pharyngeal edema, have been reported. Physicians should be vigilant for such manifestations.

Drug interaction: CYP2C8 Inhibitors: Avoid if possible; if necessary, reduce **enzalutamide** dose to 40 mg daily.

Pregnancy & lactation: Pregnancy: **Enzalutamide** is contraindicated in pregnant women due to potential fatal harm. Breast-Feeding: Not recommended in women; no evidence of harm in humans, but caution based on rat studies.

Symptoms and treatment of overdose: There is no antidote for **enzalutamide**.

Storage: Store below 30°C. Protect from light and moisture. Keep all medicine out of reach & sight of children.

Pack size: Aluminium PVC Blister of 28 Capsules with pack insert.

Before prescribing, please consult full prescribing information available from Amneal Healthcare Private Limited Regd. Office: 9th Floor, 901 to 905, Iscon Elegance, Circle P, S.G. Highway, Ahmedabad – 380015.

To be sold by retail on the prescription of an Oncologist only.

ENZANEAL™ 160

Enzalutamide Tablets 160 mg

Presentation: Each film-coated tablet contains:

Enzalutamide.....160 mg

Excipients.....q.s.

Colors: Red Oxide of Iron, Yellow Oxide of Iron & Titanium Dioxide I.P.

Pharmaceutical form: Film coated tablet.

Indications: Enzalutamide is indicated for •Treatment of adult men with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy. •The treatment of adult men with high-risk non-metastatic castration-resistant prostate cancer (CRPC). •The treatment of adult men with metastatic CRPC who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated. •The treatment of adult men with metastatic CRPC whose disease has progressed on or after docetaxel therapy.

Dosage and administration: The recommended dose is 160 mg as a single oral daily dose. Medical castration with an LHRH analogue should continue for non-surgically castrated patients.

Contraindications: Hypersensitivity to the active substance or any excipients, Women who are or may become pregnant.

Warnings & precautions: Seizure Risk: Use of **enzalutamide** is associated with seizures; decisions to continue treatment in such cases should be individualized. Posterior Reversible Encephalopathy Syndrome (PRES): Diagnosis requires brain imaging; **enzalutamide** discontinuation is recommended for patients developing PRES. Second Primary Malignancies: Patients should promptly report signs of gastrointestinal bleeding, haematuria, or other symptoms during treatment.

Drug interactions: Other Medicinal Products Affecting **Enzalutamide:** CYP2C8 inhibitors may require dose reduction; caution with P-gp substrates and QT-prolonging drugs.

Pregnancy & lactation: Contraindicated in pregnant women, Not recommended for women; potential harm to the unborn child.

Symptoms and treatment of overdose: No specific antidote; discontinue treatment and initiate supportive measures, Increased seizure risk in overdose; consider patient monitoring.

Storage: Store below 30°C

Pack size: Blister pack of 7 Tablets

Before prescribing, please consult full prescribing information available from Amneal Healthcare Private Limited Regd. Office: 9th Floor, 901 to 905, Iscon Elegance, Circle P, S.G. Highway, Ahmedabad – 380015.

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