

ABIRANEAL™ - 250

Abiraterone Acetate Tablets I.P. 250 mg

Presentation: Each uncoated tablet contains:

Abiraterone Acetate I.P.250 mg
Excipients q.s.

ABIRANEAL™ - 500

Abiraterone Acetate Tablets I.P. 500 mg

Presentation: Each film-coated tablet contains:

Abiraterone Acetate I.P. 500 mg
Excipients q.s.

Colour: Titanium Dioxide I.P.

Pharmaceutical form: Tablets

Indications: Abiraterone acetate tablets are indicated in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC) C for the treatment of mCRPC in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy.

Dosage and administration: The recommended dose is 1,000 mg (two 500 mg tablets) as a single daily dose that must not be taken with food. For mCRPC, abiraterone is used with 10 mg prednisone or prednisolone daily.

Method of administration: For oral administration only.

Contraindications: • Hypersensitivity to the active substance or to any of the excipients • Women who are or may potentially be pregnant. • Severe hepatic impairment [Child-Pugh Class C] • Abiraterone with prednisone or prednisolone is contraindicated in combination with Ra-223.

Warnings & precautions: Abiraterone may cause hypertension, hypokalemia, and fluid retention as a consequence of increased mineralocorticoid levels resulting from CYP17 inhibition. Abiraterone should be used with caution in patients with a history of cardiovascular disease. Anaemia, decreased bone density, and sexual dysfunction may occur in men with metastatic prostate cancer.

Drug interaction: Administration with food significantly increases the absorption of abiraterone acetate therefore the product must not be taken with food. Strong inducers of CYP3A4 (e.g., phenytoin, carbamazepine, rifampicin, rifabutin, rifapentine, phenobarbital, St John's wort [*Hypericum perforatum*]) during treatment are to be avoided.

Spirolactone binds to the androgen receptor and may increase prostate-specific antigen (PSA) levels

hence use with Abiraterone is not recommended.

Pregnancy & lactation: Pregnancy: Abiraterone is not for use in women and is contraindicated in women who are or may potentially be pregnant. Breastfeeding: Abiraterone is not for use in women. It is not known if abiraterone acetate is excreted in human milk.

Symptoms and treatment of overdose: Human experience of overdose with abiraterone is limited. There is no specific antidote. In the event of an overdose, administration should be withheld, and general supportive measures undertaken.

Storage: Store protected from light and moisture, at a temperature not exceeding 30°C. Keep out of reach of children.

Pack size: ABIRANEAL-250 - HDPE container pack of 120 tablets. ABIRANEAL-500 - HDPE container pack of 60 tablets.

Before prescribing, please consult full prescribing information available from Amneal Healthcare Private Limited (Formerly known as Amneal Biologics 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.