Dr.Reddy's

ABIRATRED®

Abiraterone Acetate Tablets 250 mg

- With Prednisone or Prednisolone for treatment of newly diagnosed high risk metastatic hormone sensitive prostate cancer (mHSPC) in adult men in combination with androgen deprivation therapy (ADT)[1]
- With Prednisone or Prednisolone for treatment of metastatic castration resistant prostate cancer (mCRPC) in adult men who are asymptomatic or mildly Symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated[1]
- The treatment of metastatic castration resistant prostate cancer (mCRPC) in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen[1]
- Recommeneded Dose is 1,000 mg/day (4 Tabs) orally once daily with Prednisone 5 mg administration orally once daily in mHSPC or Prednisone or Prednisolone is 10 mg daily in mCRPC[1]
- Abiratred is bioequivalent to Reference Product[2]

References:

1. Approved PI Abiratred, Revised document October, 2019
2. Shafig S. An open label, balanced, randomized, two-treatment, four-period, two-sequence, single dose, full replicate, oral Bioequivalence Study of Abiraterone Acetate Tablets 250 mg of Dr. Reddy's Laboratories Limited, India comparing with ZYTIGA™ (Abiraterone acetate) tablets 250 mg of JANSSEN-CILAG PHARMACEUTICAL LTD. Gerivatiba street, 207, Sao Paulo - SP in healthy, adult, male human subjects under fasting conditions. BE study report. Veeda Clinical Research Pvt. Ltd, Project No. 16-VIN-0402.

Dr.Reddy's

Bioequivalence Study Summary

Dr.Reddy's Abiraterone vs. Reference Drug[2]

Dosage Form

Tablet

Dr Reddy's ⟺ Reference Drug

Extent of Absorption (AUC_{0-t})
90% CI for (T/R)

With in BE Range*

Dr Reddy's ⟺ Reference Drug

Strength

250 mg

Dr Reddy's ⟺ Reference Drug

Rate of Absorption (Cmax)
90% CI for (T/R)

With in BE Range#

Dr Reddy's ⟺ Reference Drug

Based on the analytical data it is concluded that Dr.Reddy's Abiraterone formulation is Pharmaceutical equivalent and Bioequivalent to Reference Product

ABIRATRED (Abiraterone Acetate) Composition: Each film coated tablet contains: Abiraterone Acetate 250 mg. **Indication:** The treatment of newly diagnosed high risk metastatic hormone sensitive prostate cancer (mHSPC) in adult men in combination with androgen deprivation therapy (ADT). The treatment of metastatic castration resistant prostate cancer (mCRPC) in adult men who are asymptomatic or mildly Symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated. The treatment of metastatic castration resistant prostate cancer (mCRPC) in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen. **Recommended dose:** for high risk metastatic HSPC 1,000 mg (four 250 mg tablets) orally once daily with prednisone 5 mg once daily. for metastatic CRPC 1,000 mg (four 250 mg tablets) orally as a single daily dose with prednisone or prednisolone is 10 mg daily. **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). **Special warnings and precautions:** Hypertension, hypokalemia, fluid retention and cardiac failure due to mineralocorticoid excess, Hepatotoxicity and hepatic impairment, Corticosteroid withdrawal and coverage of stress situations, Bone density, Prior use of ketoconazole, Hyperglycemia, Use with chemotherapy , Potential risks, Skeletal muscle effects, Interactions with other medicinal products **Drug interaction:** In a clinical pharmacokinetic interaction study of healthy subjects pretreated with a strong CYP3A4 inducer rifampicin. 600 mg daily for 6 days followed by a single dose of abiraterone acetate 1,000 mg, the mean plasma AUC_{∞} of abiraterone was decreased by 55%. an inhibitor of the hepatic drug–metabolizing enzymes CYP2D6 and CYP2CB. **Pregnancy and lactation :** Abiraterone is not for use in women. **Ability to drive and use machines:** Abiraterone has no or negligible influence on the ability to drive or use machines. **Adverse reactions:** The most common adverse reactions seen are peripheral edema, hypokalemia, hypertension and urinary tract infection. Other important adverse reactions include, cardiac disorders, hepatotoxicity, fractures, and allergic alveolitis. **Storage Condition:** Store below 30°C. **Precautions for Storage:** Protect from light and moisture. Keep out of reach of children.

โปรดอ่านรายละเอียดเพิ่มเติมในเอกสารอ้างอิงฉบับสมบูรณ์และเอกสารกำกับยา

ยาควบคุมพิเศษ ใช้เฉพาะในโรงพยาบาล

ใบอนุญาตโฆษณาเลขที่ ฆศ. 0247/2563

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