- Patients should be informed that in the event of a missed daily dose of Abiraterone acetate or prednisone, they should take their normal dose the following day. If more than one daily dose is skipped, patients should be told to inform their physician.
- Patients should be apprised of the common side effects associated with Abiraterone acetate including peripheral edema, hypokalemia, hypertension, elevated liver function tests, and urinary tract infection. Direct the patient to a complete list of adverse reactions in PATIENT INFORMATION.
- Patients should be advised that their liver function will be monitored using blood tests.
- Patients should be informed that Abiraterone acetate may harm a developing fetus; thus, women who are pregnant or women who may be pregnant should not handle Abiraterone acetate without protection, e.g., gloves. Patients should also be informed that it is not known whether abiraterone or its metabolites are present in semen and they should use a condom if having sex with a pregnant woman. The patient should use a condom and another effective method of birth control if he is having sex with a woman of child-bearing potential. These measures are required during and for one week after treatment with Abiraterone acetate.

PRESENTATION :
Abiraterone acetate tablets IP 250 mg are available in HDPE bottles of 120 tablets.

Manufactured in India by:
BETA DRUGS LTD
Kharuni - Lodhimajra Road, Vil. Nandpur,
Baddi, Distt Solan, Himachal Pradesh-
173205

Marketed by:
NEOVA BIOGENE PRIVATE LIMITED.
Monte Plaza, MM Malviya Marg,
Mulund(W) Mumbai-80. India.

For the use only of an Oncologist or a Hospital or a Laboratory

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Abiraterone Acetate Tablets IP

BIRAFINE 250mg

WARNINGS AND PRECAUTIONS

Hypertension, Hypokalemia and Fluid Retention Due to Mineralocorticoid Excess :

Abiraterone acetate may cause hypertension, hypokalemia, and fluid retention as a consequence of increased mineralocorticoid levels resulting from CYP17 inhibition.

Adrenocortical Insufficiency :

Adrenal insufficiency occurred in the two randomized clinical studies in 0.5% of patients taking Abiraterone acetate and in 0.2% of patients taking placebo. Adrenocortical insufficiency was reported in patients receiving Abiraterone acetate in combination with prednisone, following interruption of daily steroids and/or with concurrent infection or stress. Use caution and monitor for symptoms and signs of adrenocortical insufficiency, particularly if patients are withdrawn from prednisone, have prednisone dose reductions, or experience unusual stress.

Hepatotoxicity :

In the two randomized clinical trials, grade 3 or 4 ALT or AST increases (at least 5× ULN) were reported in 4% of patients who received Abiraterone acetate, typically during the first 3 months after starting treatment. Patients whose baseline ALT or AST were elevated were more likely to experience liver test elevation than those beginning with normal values. Treatment discontinuation due to liver enzyme increases occurred in 1% of patients taking Abiraterone acetate. No deaths clearly related to Abiraterone acetate were reported due to hepatotoxicity events.

Pregnancy :

Abiraterone acetate may harm a developing fetus : thus women who are pregnant or women who may be pregnant should not handle Abiraterone acetate without protection, e.g. gloves. Women of child-bearing potential should avoid becoming pregnant during treatment.

COMPOSITION

Abiraterone acetate

Each uncoated Tablet contains:

Abiraterone acetate	IP	250 mg
Excipients		qs

DESCRIPTION

Abiraterone acetate is an antiandrogen used in the treatment of Castration-Resistant Prostate Cancer(CRPC).

CLINICAL PHARMACOLOGY

Mechanism of Action

Abiraterone acetate is converted *in vivo* to abiraterone, an androgen biosynthesis inhibitor, that inhibits 17 α-hydroxylase/C17,20-lyase (CYP17). This enzyme is expressed in testicular, adrenal, and prostatic tumor tissues and is required for androgen biosynthesis.

PHARMACOKINETICS

Absorption : Good oral bioavaliability with peak plasma levels seen within 2 hours of administration. Systemic exposure of Abiraterone is increased when administrated with food.
Distribution : Highly plasma protein food(>90%).
Metabolism : Following oral administration, Abiraterone acetate is hydrolyzed to its active metabolite Aberiterone. CYP3A4 and SULT2A1 are the enzymes involved in the metabolism.
Half-life : The mean terminal half-life of Abiraterone is 7 to 17 hours.
Elimination : Mainly excreted in the feces (88%) and approximately 5% in urine.

INDICATIONS AND USAGE

Abiraterone acetate is a CYP17 inhibitor indicated in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer.

DOSAGE AND ADMINISTRATION

Recommended Dosage

The recommended dose of Abiraterone acetate is 1,000 mg (four 250 mg tablets) administered orally once daily in combination with prednisone 5 mg administered orally twice daily.

Administration : Abiraterone acetate must be taken on an empty stomach. No food should be consumed for at least two hours before the dose of Abiraterone acetate is taken and for at least one hour after the dose of Abiraterone Acetate is taken. The tablets should be swallowed whole with water. Do not crush or chew tablets.