ABATITOR

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for ABATITOR (Abiraterone Acetate Tablets U.S.P.)
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Abiraterone is an androgen biosynthesis inhibitor which selectively inhibits the enzyme 17-α-hydroxylase/ C17, 20lyase (CYP17). This enzyme is expressed in and is required for androgen biosynthesis in testicular, adrenal and prostatic tumour tissues. Treatment with abiraterone decreases serum testosterone to undetectable levels (using commercial assays) when given with LHRH analogues (or orchiectomy).

INDICATIONS: For the treatment of metastatic castration resistant prostate cancer in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated, with prednisone or prednisolone.

DOSAGE AND ADMINISTRATION: As directed by physician, the recommended dose is 1,000 mg as a single daily dose that must not be taken with food. Taking the tablets with food increases systemic exposure to abiraterone. Dose should be taken orally The tablets should be taken at least one hour before or at least two hours after eating. These should be swallowed whole with water.

CONTRAINDICATION: ABATITOR should not be used in 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, hypokalaemia and fluid retention as a consequence of increased mineralocorticoid levels resulting from cyp17 inhibition. Caution in patients with a history of cardiovascular disease. If patients develop severe hepatotoxicity anytime while on therapy, treatment should be discontinued and patients should not be re-treated, Patients with severe hepatic impairment should not be using this drug. Caution is advised and monitoring for adrenocortical insufficiency should occur if patients are withdrawn from prednisone or prednisolone. If abiraterone is continued after corticosteroids are withdrawn, patients should be monitored for symptoms of mineralocorticoid excess. Decreased bone density may occur in men with metastatic advanced prostate cancer. In combination with a glucocorticoid could increase this effect, lower rates of response might be expected in patients previously treated with ketoconazole for prostate cancer, he use of glucocorticoids could increase hyperglycaemia, therefore blood sugar should be measured frequently in patients with diabetes. Patients with rare hereditary problems of galactose intolerance, the lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine as it contains lactose. Anaemia and sexual dysfunction may occur in men with metastatic prostate cancer including those undergoing treatment with abiraterone, caution is recommended in patients concomitantly treated with medicinal products known to be associated with myopathy/rhabdomyolysis

DRUG INTERACTIONS: *Potential for other medicinal products to affect abiraterone exposures* Strong inducers of CYP3A4 (e.g., phenytoin, carbamazepine, rifampicin, rifabutin, rifapentine, phenobarbital, St John's wort) during treatment are to be avoided, unless there is no therapeutic alternative. *Potential to affect exposures to other medicinal products* Dose reduction of medicinal products with a narrow therapeutic index that are metabolised by CYP2D6 (metoprolol, propranolol, desipramine, venlafaxine, haloperidol, risperidone, propafenone, flecainide, codeine, oxycodone and tramadol) should be considered. patients should be monitored for signs of toxicity related to a CYP2C8 substrate with a narrow therapeutic index if used concomitantly. *In vitro*, the major metabolites abiraterone sulphate and Noxide abiraterone sulphate were shown to inhibit the hepatic uptake transporter OATP1B1 and as a consequence it may

increase the concentrations of medicinal products eliminated by OATP1B1. *Use with products known to prolong QT interval:* drugs known to prolong the QT interval or medicinal products able to induce torsades de pointes such as class IA (e.g. quinidine, disopyramide) or class III (e.g. amiodarone, sotalol, dofetilide, ibutilide) antiarrhythmic medicinal products, methadone, moxifloxacin, antipsychotics, etc. *Use with Spironolactone:* Spironolactone with abiraterone is not recommended.

ADVERSE REACTIONS: Urinary tract infection, sepsis, adrenal insufficiency, hypokalaemia, hypertriglyceridemia, cardiac failure*, angina pectoris, atrial fibrillation, tachycardia uncommon: other arrhythmias, myocardial infarction, QT prolongation, hypertension, allergic alveolitisa, diarrhoea, dyspepsia, alanine aminotransferase increased, aspartate aminotransferase increased, hepatitis fulminant, acute hepatic failure, rash, myopathy, rhabdomyolysis, haematuria, oedema peripheral, fractures.

MARKETED BY:

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(Additional information is available on request)