Abiraterone Acetate Tablets USP, 250 mg

S.No.	Category	Question	Answer
Clinical Particulars			
1	Use/Indication	What is the product indicated for?	Abiraterone acetate tablets is indicated in combination with prednisone for the treatment of patients with Metastatic castration-resistant prostate cancer (CRPC)
2	Dosage	What is the recommended dosage?	The recommended dose of abiraterone acetate tablets is 1,000 mg (two 500 mg tablets or four 250 mg tablets) orally once daily with prednisone 5 mg orally twice daily.
3	Administration	How do I take it?	Take abiraterone acetate tablets on an empty stomach, either one hour before or two hours after a meal. Swallow tablets whole with water
4	Formulation	Can tablet be crushed?	Do not crush or chew the tablets
5	Administration	What do I do if I miss a dose?	If you miss a dose of abiraterone acetate tablets continue your prescribed course of therapy, and contact your physician immediately.
6	Administration	Use in Pediatric Population	Safety and effectiveness of abiraterone acetate in pediatric patients have not been established.
7	Administration	Use in Geriatric Population	No overall differences in safety or effectiveness were observed between these elderly patients and younger patients. Other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.
8	Mechanism	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. CYP17 catalyzes two sequential reactions: 1) the conversion of pregnenolone and progesterone to their 17α-hydroxy derivatives by 17α-hydroxylase activity and 2) the subsequent formation of dehydroepiandrosterone (DHEA) and androstenedione, respectively, by C17, 20 lyase activity. DHEA and androstenedione are androgens and are precursors of testosterone. Inhibition of CYP17 by abiraterone can also result in increased mineralocorticoid production by the adrenals. Androgen sensitive prostatic carcinoma responds to treatment that decreases androgen levels. Androgen deprivation therapies, such as treatment with

			GnRH agonists or orchiectomy, decrease androgen production in the testes but do not affect androgen production by the adrenals or in the tumor. Abiraterone acetate decreased serum testosterone and other androgens in patients in the placebo controlled clinical trial. It is not necessary to monitor the effect of abiraterone acetate on serum testosterone levels. Changes in serum prostate specific antigen (PSA) levels may be observed but have not been shown to correlate with clinical benefit in individual patients.
9	Warning	Black Box Warning	None
10	Lactation	Use in Lactation	Not Indicated for Women
11	Pregnancy	Use in Pregnancy	Abiraterone acetate is contraindicated for use in pregnant women because the drug can cause fetal harm and potential loss of pregnancy. Abiraterone acetate is not indicated for use in females
12	Precautions	Is there any interaction between medication and alcohol?	None
13	Interaction	Is there any interaction with food?	Abiraterone acetate taken with food causes increased exposure and may result in adverse reactions. Take abiraterone acetate tablets on an empty stomach, either one hour before or two hours after a meal
14	Side effects	What are the common side effects?	Feeling very tired, vomiting, joint pain o infected nose, sinuses or throat (cold), high blood pressure, cough, nausea o headache, swelling in your legs or feet, low red blood cells (anemia), low blood potassium levels, high blood cholesterol and triglycerides, hot flushes, high blood sugar levels, diarrhea, certain other abnormal blood tests
15	Storage	What are the storage conditions?	Store at 20°C to 25°C (68°F to 77°F); excursions permitted in the range from 15°C to 30°C (59°F to 86°F)
16	Dispensing	How to Dispense?	As prescribed by the Physician
17	Contraindication	What are the contraindications of (medication).	Contraindicated in pregnancy
Pharmaceutical Particulars			
18	Pharmaceutical Form	How is it supplied?	Abiraterone acetate 250 mg uncoated Tablets USP White to off-white, oval tablets debossed with “ABR” on one side and “250” on other side. Abiraterone acetate 250 mg tablets USP are available in high-density polyethylene bottles of 120 tablets. NDC Number 72205-030-92
19	Ingredients	Active and Inactive Ingredients	**Active**: Abiraterone Acetate **Inactive**: colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, and sodium lauryl sulfate.
20	Coating	What is the type of coating?	Uncoated tablets
Allergens			
21	Ingredients	Is it Vegetarian?	No, Lactose produced from milk, that has been sourced

			from healthy cows is used as inactive ingredient.
22	Ingredients	Does it contain Gluten?	No
23	Ingredients	Does it contain Dairy Products?	Yes, Lactose produced from milk, that has been sourced from healthy cows is used as inactive ingredient.
24	Ingredients	Does it contain Casein	No
25	Ingredients	Does it contain Whey?	No
26	Ingredients	Does it contain corn?	No
27	Ingredients	Does it contain rye?	No
28	Ingredients	Does it contain sugar?	Yes
29	Ingredients	Does it contain Oats?	No
30	Ingredients	Does it contain wheat?	No
31	Ingredients	Does it contain spelt?	No
32	Ingredients	Does it contain barley?	No
33	Ingredients	Does it contain rennet?	No
34	Ingredients	Does it contain starch?	No
35	Ingredients	Does it contain contain povidone?	Yes
36	Ingredients	Does it contain Iodine?	No
37	Ingredients	Does it contain latex?	No
38	Ingredients	Does it contain alcohol?	Yes
39	Ingredients	Does it contain dyes?	No
40	Ingredients	Does it contain flavor?	No
41	Ingredients	Does it contain Lactose?	Yes, Lactose produced from milk, that has been sourced from healthy cows is used as inactive ingredient.
42	Ingredients	Does it contain Nuts?	No
43	Ingredients	Does it contain Preservatives?	No
44	Ingredients	Does it contain Soy products?	No
45	Ingredients	Does it contain peanut?	No
46	Ingredients	Does it contain nickel?	No
Miscellaneous			
47	Miscellaneous	May I know the product availability?	Novadoz Pharmaceuticals products are only available through pharmacies, wholesalers, and other authorized distributors. See our ADR (authorized distributors of record) page at NovadozPharma.com to learn more about where to find our products.

48	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
49	Miscellaneous	Do you have any patient's assistance program?	Novadoz Pharmaceuticals does not offer patient assistance programs at this time. The company that produces the brand version of your product may or may not offer such a program. Please check for access & eligibility requirements with that company.
50	Miscellaneous	How do I report an adverse drug effect or reaction to Novadoz medication?	To report suspected adverse reactions, contact Novadoz Pharmaceuticals LLC at 1-855-668-2369 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
51	Miscellaneous	Why does my pharmacy that used to fill your generic formulation of a particular medicine, no longer fills my prescription with Novadoz formulation?	Please check with your pharmacy as to why your prescription is not a Novadoz Pharmaceuticals product. You may refer to NovadozPharma.com ADR (authorized distributor of record) page to learn where to find our products.
52	Miscellaneous	Manufacturer and Distributor	**Manufactured by:** MSN Laboratories Private Limited Ranga Reddy (Dt.) Telangana – 509 228, INDIA **Distributed by:** Novadoz Pharmaceuticals LLC Piscataway, NJ 08854-3714