Capecitabine Tablets USP, 150 mg and 500 mg

S.No.	Category	Question	Answer
		Clinical Particulars	
1	Use/Indication	What is the product indicated for?	**Colorectal Cancer** Capecitabine tablets are indicated as a single agent for adjuvant treatment in patients with Dukes' C colon cancer who have undergone complete resection of the primary tumor when treatment with fluoropyrimidine therapy alone is preferred, in the first-line treatment of patients with metastatic colorectal carcinoma when treatment with fluoropyrimidine therapy alone is preferred. **Breast Cancer** Capecitabine tablets in combination with docetaxel are indicated for the treatment of patients with metastatic breast cancer after failure of prior anthracycline-containing chemotherapy. Capecitabine tablets monotherapy is also indicated for the treatment of patients with metastatic breast cancer resistant to both paclitaxel and an anthracycline-containing chemotherapy regimen or resistant to paclitaxel and for whom further anthracycline therapy is not indicated (e.g., patients who have received cumulative doses of 400 mg/m2 of doxorubicin or doxorubicin equivalents).
2	Dosage	What is the recommended dosage?	As monotherapy in metastatic colorectal cancer, adjuvant colorectal cancer and metastatic breast cancer the recommended dose of capecitabine tablets are 1250mg/m2 administered orally twice daily (morning and evening; equivalent to 2500mg/m2 total daily dose) for 2 weeks followed by a 1-week rest period given as 3-week cycles. Adjuvant treatment in patients with Dukes' C colon cancer it is recommended for a total of 8 cycles (i.e. 6months). In combination with Docetaxel in metastatic breast cancer the recommended dose of capecitabine tablets are 1250mg/m2 administered orally twice daily for 2 weeks followed by a 1-week rest period combined with docetaxel at 75mg/m2 as a 1-hour intravenous infusion every 3 weeks.
3	Administration	How to Administer	Take capecitabine tablets 2 times a day, 1 time in the morning and 1 time in the evening. Capecitabine tablets should be swallowed whole with water within 30 minutes after a meal. If Capecitabine tablets must be cut or crushed, this should be done by a professional trained in safe handling of cytotoxic drugs using appropriate equipment and safety procedures.
4	Administration	Use in Paediatric Population	According to PI the safety and effectiveness of capecitabine have not been established in paediatrics.
5	Administration	Use in Geriatric Population	According to the PI caution is advised when capecitabine is used in geriatric population due to high incidence of adverse effects.

6	Mechanism	Mechanism of Action	Enzymes convert capecitabine to 5-fluorouracil (5-FU) in vivo. Both normal and tumor cells metabolize 5-FU to 5-fluoro-2'-deoxyuridine monophosphate (FdUMP) and 5-fluorouridine triphosphate (FUTP). These metabolites cause cell injury by two different mechanisms. First, FdUMP and the folate cofactor, N5-10-methylenetetrahydrofolate, bind to thymidylate synthase (TS) to form a covalently bound ternary complex. This binding inhibits the formation of thymidylate from 2'-deoxyuridylate. Thymidylate is necessary precursor of thymidylate triphosphate, which is essential for the synthesis of DNA, so that a deficiency of this compound can inhibit cell division. Second, nuclear transcriptional enzymes can mistakenly incorporate FUTP in place of uridine triphosphate (UTP) during the synthesis of RNA. This metabolic error can interfere with RNA processing and protein synthesis.
7	Warning	Black Box Warning	**Capecitabine Warfarin Interaction:** Patients receiving concomitant capecitabine and oral coumarin-derivative anticoagulant therapy should have their anticoagulant response (INR or prothrombin time) monitored frequently in order to adjust the anticoagulant dose accordingly. Altered coagulation parameters and/or bleeding, including death, have been reported in patients taking capecitabine concomitantly with coumarin-derivative anticoagulants such as warfarin and phenprocoumon. Postmarketing reports have shown clinically significant increases in prothrombin time (PT) and INR in patients who were stabilized on anticoagulants at the time of capecitabine was introduced. These events occurred within several days and up to several months after initiating capecitabine therapy and, in a few cases, within 1 month after stopping capecitabine. These events occurred in patients with or without liver metastases. Age greater than 60 and a diagnosis of cancer independently predispose patients to an increased risk of coagulopathy.
8	Lactation	Use in Lactation	There is no information regarding the presence of capecitabine in human milk, or on its effects on milk production or the breast fed infant.
9	Pregnancy	Use in Pregnancy	Capecitabine can cause fetal harm when administered to a pregnant woman. Females of reproductive potential are advised to use effective contraception during treatment and for 6 months following the final dose of capecitabine. Male patients of female reproductive potential are advised to use effective contraception during treatment and for 3 months following the final dose of capecitabine.
10	Precautions	Is there any interaction between medication and alcohol.	No
11	Storage	What are the storage conditions?	Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F).
12	Dispensing	How to Dispense?	As prescribed by the Physician
13	Contraindication	What are the contraindications of (medication)?	Capecitabine is contraindicated in patients with severe renal impairment and in patients with known hypersensitivity to capecitabine or to any of its components. Capecitabine is contraindicated in patients who have known hypersensitivity to 5-fluorouracil.
14	Side Effects	What are the common side effects of Capecitabine?	The most common side effects of capecitabine tablets include: diarrhea, hand and foot syndrome, nausea, vomiting, stomach-area (abdominal) pain, tiredness, weakness, increased amounts of red blood cell breakdown products (bilirubin) in your blood.
15	Administration	What do I do if I miss a dose?	If you miss a dose of Capecitabine, continue your prescribed course of therapy, and contact your physician immediately.
Pharmaceutical Particulars			

16	Pharmaceutical Form	How is it supplied	Capecitabine tablets 150 mg are supplied as Light peach to peach colored, oblong shaped, biconvex film coated tablets, debossed with “C” on one side and “150” on other side. Bottles of 60 tablets NDC-72205-006-60. Capecitabine tablets 500 mg are supplied as Light peach to peach colored, oblong shaped, biconvex film coated tablets, debossed with “C” on one side and “500” on other side. Bottles of 120 tablets NDC-72205-007-92.
17	Ingredients	Active and Inactive ingredients	**Active**: Capecitabine. **Inactive:** Anhydrous lactose, croscarmellose sodium, hypromellose, magnesium stearate and microcrystalline. The peach or light peach film coating contains hypromellose, talc, titanium dioxide, iron oxide red, ferrosoferric oxide and iron oxide yellow.
18	Coating	What is the type of coating?	The product is film coated to peach or light peach colour.
Allergens			
19	Labeling	Are there any excipients not listed in the USPI?	No. All the excipients used are listed in USPI.
20	Ingredients	Does it contain Kosher?	No
21	Ingredients	Is it Vegetarian?	Yes
22	Ingredients	Does it contain Gluten?	No
23	Ingredients	Does it contain starch?	No
24	Ingredients	Does the product contain povidone?	No
25	Ingredients	Does the product contain Iodine?	No
26	Ingredients	What is the source of starch?	No
27	Ingredients	Does it contain latex?	No
28	Ingredients	Does it contain alcohol?	No
29	Ingredients	Does it contain dyes?	No
30	Ingredients	Does it contain flavor?	No
31	Ingredients	Does it contain Lactose?	Yes
32	Ingredients	Does it contain Nuts?	No
33	Ingredients	Does it contain Preservatives?	Yes
34	Ingredients	Does it contain Shell Fish?	No
35	Ingredients	Does it contain Soy products?	No
36	Prescribing Information	Are there any Older USPI's available?	No
37	Ingredients	Does it contain peanut?	No
38	Ingredients	Are all excipients are free from human or animal origin?	Yes

39	Ingredients	Does it contain Yellow dye?	No
40	Ingredients	Does it contain any derivatives from tree nuts or any other type of nuts?	No
41	Ingredients	Does it contain red dye?	No
42	Ingredients	Does it contain nickel?	No
43	Odour	Does the tablet have fishy odour	No
Miscellaneous			
44	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.
45	Miscellaneous	May I know about return, refunds and reimbursement ?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500.
46	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.
47	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.
48	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.
49	Miscellaneous	Manufacturer and Distributor	**Manufactured by:** MSN Laboratories Private Limited, Telangana, 509 216, India. **Distributed by:** Novadoz Pharmaceuticals LLC Piscataway, NJ 08854-3714