

TOREMIFENE CITRATE – Tablet 60mg

S.No.	Category	Question	Answer
Clinical Particulars			
1	Use/Indication	What is the product indicated for?	Toremifene citrate tablets are estrogen agonist/antagonist indicated for the treatment of metastatic breast cancer in postmenopausal women with estrogen-receptor positive or unknown tumors.
2	Dosage	What is the recommended dosage?	The dosage of Toremifene citrate tablets are 60 mg, once daily, orally. Treatment is generally continued until disease progression is observed.
3	Administration	How do I take it?	Take one Toremifene citrate tablet orally once a day, as directed by your doctor. Swallow the tablet 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, just take your next dose at the regular time. Do not double up or take two doses at once unless directed by your provider.
6	Administration	Use in Pediatric Population	There is no indication for use of Toremifene citrate in pediatric patients.
7	Administration	Use in Geriatric Population	Toremifene was studied in young men and older women after a single dose. In older women, the drug stayed in the body longer and spread more in the body, but overall exposure and clearance were similar. Studies in patients aged 60–66 years showed no major differences in effectiveness or safety with age.
8	Mechanism	Mechanism of Action	Toremifene is a non-steroidal drug that acts on estrogen receptors. It can show both estrogen-like and anti-estrogen effects depending on the situation, but in humans it mainly works as an anti-estrogen. It helps treat breast cancer by blocking estrogen from binding to cancer cells, which slows or stops their growth.
9	Warning	Black Box Warning	Toremifene citrate has been shown to prolong the QTc interval in a dose- and concentration-related manner. Prolongation of the QT interval can result in a type of ventricular tachycardia called Torsade de pointes, which may result in syncope, seizure, and/or death. Toremifene should not be prescribed to patients with congenital/acquired QT prolongation, uncorrected hypokalemia or uncorrected hypomagnesemia. Drugs known to prolong the QT interval and strong CYP3A4 inhibitors should be avoided.

10	Lactation	Use in Lactation	It is not known if Toremifene passes into human breast milk, but it is found in animal studies. Since it may harm the baby, the mother should either stop breastfeeding or stop the drug, taking into account the importance of the drug to the mother.
11	Pregnancy	Use in Pregnancy	Toremifene may harm an unborn baby. Animal studies showed pregnancy loss and birth defects even at low doses. There are no proper studies in pregnant women, so it should be avoided. If used during pregnancy, the patient should be warned about the risk to the baby.
12	Precautions	Is there any interaction between medication and alcohol?	• Drugs that reduce calcium excretion (e.g., thiazide diuretics): Increase the risk of hypercalcemia. • QT-prolonging drugs: Avoid combination due to increased risk of QT prolongation/arrhythmias; if unavoidable, monitor with ECGs. • Strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin,): Decrease toremifene levels, reducing effectiveness. • Strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin, ritonavir, grapefruit juice): Increase toremifene levels, raising the risk of QT prolongation; avoid if possible. • Effect on CYP3A4 substrates: Toremifene has no clinically significant effect on CYP3A4 substrate drugs. • Effect on CYP2C9 substrates: Toremifene is a weak CYP2C9 inhibitor; use caution with warfarin and phenytoin, and monitor closely.
13	Interaction	Is there any interaction with food?	• Toremifene tablets may be taken with or without food. • Food does not affect the rate and extent of absorption. • Patients should avoid grapefruit products and other foods that are known to inhibit CYP3A4 during toremifene citrate treatment.
14	Side effects	What are the common side effects?	Toremifene tablets can cause serious side effects, including: • QT prolongation: Can affect heart rhythm (dangerous heartbeat). • Hepatotoxicity: May cause liver damage. • Hypercalcemia & tumour flare: Can increase calcium levels and temporarily worsen symptoms. • Uterine cancer risk: May increase risk of cancer in the uterus.

			• General: Use with caution. • Lab tests: Regular blood tests may be needed. • Pregnancy: Can harm the baby—do not use during pregnancy. • Women (childbearing age): Use non-hormonal birth control while taking this drug.)
15	Storage	What are the storage conditions?	Store at room temperature (around 25°C). It can be kept between 15–30°C (59-86°F). Keep it away from heat and light.
16	Dispensing	How to Dispense?	As prescribed by the Physician.
17	Contraindication	What are the contraindications of (medication).	• Hypersensitivity to the drug. • Toremifene should not be prescribed to patients with congenital/acquired QT prolongation (long QT syndrome), uncorrected hypokalemia, or uncorrected hypomagnesemia.
Pharmaceutical Particulars			
18	Pharmaceutical Form	How is it supplied?	Toremifene Tablets 60 mg: The tablet is White(white to off-white), round, and uncoated, debossed with “MT” on one side and plain on the other side, and free from physical defects. NDC: 72205-050.
19	Ingredients	Active and Inactive Ingredients	Active Ingredients: Toremifene Inactive Ingredients: The tablets contain Cellulose, Microcrystalline; Lactose monohydrate; Sodium Starch glycolate (type a, potato); Corn starch; Povidone k30, Silicon dioxide, Magnesium stearate.
20	Coating	What is the type of coating?	Film coated tablets
Allergens			
21	Ingredients	Is it Vegetarian?	No
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.)
24	Ingredients	Does it contain Casein	No
25	Ingredients	Does it contain Whey?	No
26	Ingredients	Does it contain corn?	Yes
27	Ingredients	Does it contain rye?	No

28	Ingredients	Does it contain sugar?	No
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?	Yes (Contains starch)
36	Ingredients	Does it contain Iodine?	No
37	Ingredients	Does it contain latex?	No
38	Ingredients	Does it contain alcohol?	Yes (API contains solvents within the limits as per ICH)
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.)
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 Telangana – 509 228, INDIA Distributed by: Novadoz Pharmaceuticals LLC Piscataway, NJ 08854-3714