

**TOREMIFENE CITRATE TABLETS, 60 mg**

S.No.	Category	Question	Answer
<b>Clinical Particulars</b>			
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 to administer?	<p>Toremifene citrate tablets are available only as tablets for oral administration and are to be taken orally as prescribed.</p> <p>Specific interactions with foods that inhibit CYP3A4, including grapefruit juice, have not been studied but may increase toremifene concentrations. Patients should avoid grapefruit products and other foods that are known to inhibit CYP3A4 during toremifene citrate treatment.</p>
4	Administration	What if you take more than you should?	<p>Contact your doctor, pharmacist or the nearest hospital immediately. Symptoms of overdose may be dizziness, ataxia, nausea, headache, hot flashes; estrogenic effects, such as vaginal bleeding.</p> <p>There is no specific antidote and the treatment is symptomatic.</p>
5	Administration	Can tablet be chewed?	Take Toremifene tablets exactly as your doctor tells you to take it.
6	Administration	Use in Pediatric Population	There is no indication for use of toremifene citrate in pediatric patients.
7	Administration	Use in Geriatric Population	The pharmacokinetics of toremifene studied in elderly patients showed no significant age-related differences in effectiveness or safety.
8	Mechanism	Mechanism of Action	Toremifene is a nonsteroidal triphenylethylene derivative. The antitumor effect of toremifene in breast cancer is believed to be mainly due to its antiestrogenic effects, i.e., its ability to compete with estrogen for binding sites in the cancer, blocking the growth-stimulating effects of estrogen in the tumor.
9	Warning	Black Box Warning	<p><b>QT prolongation</b></p> <p>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 <i>Torsade de pointes</i>, which may result in syncope, seizure, and/or death. Toremifene</p>

			<p>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</p> <p>For more details, see warnings and precautions (5.1) in Full Prescribing Information.</p>
10	Lactation	Use in Lactation	<p>It is not known if toremifene is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from toremifene citrate, a decision should be made to either discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.</p>
11	Pregnancy	Use in Pregnancy	<p>Fetal harm may occur when administered to a pregnant woman. Women should be advised not to become pregnant when taking toremifene citrate.</p> <p>Women of Childbearing Potential: Toremifene citrate is indicated only in postmenopausal women. However, premenopausal women prescribed toremifene citrate should use effective non-hormonal contraception and should be apprised of the potential hazard to the fetus if pregnancy occurs.</p>
12	Precautions	Is there any interaction between medication and alcohol.	Not available
13	Storage	What are the storage conditions?	<p>Store at 25°C (77°F). Excursions permitted to 15-30°C (59-86°F) [See USP Controlled Room Temperature.]</p> <p>Protect from heat and light.</p>
14	Dispensing	How to Dispense?	Dispensed in sealed bottle. Do not accept the bottle if seal over bottle is broken or missing.
15	Contraindication	What are the contraindications of (medication)?	<p><b><u>Hypersensitivity to the Drug</u></b> Toremifene citrate is contraindicated in patients with known hypersensitivity to the drug.</p> <p><b><u>QT Prolongation, Hypokalemia, Hypomagnesemia</u></b> Toremifene should not be prescribed to patients with congenital/acquired QT prolongation (long QT syndrome), uncorrected hypokalemia, or uncorrected hypomagnesemia.</p>
16	Drug Interactions	Any Drug Interactions?	<ul style="list-style-type: none"> <li>• Drugs that decrease renal calcium excretion, e.g., thiazide diuretics, may increase the risk of hypercalcemia in patients receiving toremifene citrate.</li> <li>• Agents that prolong QT should be avoided.</li> <li>• Coadministration with a strong CYP3A4 inducer may result in a relevant decrease in toremifene citrate exposure and should be avoided.</li> <li>• Coadministration with a strong CYP3A4</li> </ul>

			<p>inhibitor can result in a relevant increase in toremifene citrate exposure and should be avoided.</p> <ul style="list-style-type: none"> <li>• CYP2C9 substrates with a narrow therapeutic index such as warfarin or phenytoin with toremifene citrate should be used with caution and require careful monitoring.</li> </ul> <p>For more details, see full Prescribing Information.</p>
<b>Pharmaceutical Particulars</b>			
17	Pharmaceutical Form	How is it supplied?	Toremifene citrate tablets are available as: NDC 72205-050-30 bottles of 30
18	Ingredients	Active and Inactive	<p>Active ingredient: Toremifene citrate</p> <p>Inactive ingredients: colloidal silicon dioxide, corn starch, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone K 30 and sodium starch glycolate.</p>
<b>Allergens</b>			
19	Ingredients	Does it contain Gluten?	No
20	Ingredients	Does it contain alcohol?	Toremifene Citrate API contains Methonal NMT 3000 PPM
21	Ingredients	Does it contain dyes?	No
22	Ingredients	Does it contain Lactose?	Yes, produced from Milk protein and used as diluent
23	Ingredients	Does it contain Nuts?	No
24	Ingredients	Does it contain Preservatives?	No
25	Ingredients	Does it contain Soy products?	No
26	Ingredients	Are all excipients are free from human or animal origin?	Yes
27	Ingredients	Other Substances	<p>Toremifene Citrate Tablets 60 mg are free from Latex, Casein, Whey, Rye, Sugar, Preservatives, Oats, Wheat, Spelt, Barley and Rennet.</p> <p>Toremifene Citrate Tablets 60 contain Starch which is derived from maize starch/corn starch.</p>
<b>Miscellaneous</b>			
28	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 <a href="http://NovadozPharma.com">NovadozPharma.com</a> to learn more about where to find our products
29	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
30	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.

31	Miscellaneous	How do I report an adverse drug effect or reaction to Novadoz medication?	To report <b>SUSPECTED ADVERSE REACTIONS</b> , contact Novadoz Pharmaceuticals LLC at 1-855-668-2369 or FDA at 1-800-FDA-1088 or <a href="http://www.fda.gov/medwatch">www.fda.gov/medwatch</a> .
32	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 <a href="http://NovadozPharma.com">NovadozPharma.com</a> ADR (authorized distributor of record) page to learn where to find our products
33	Miscellaneous	May I know where is this product manufactured?	<p><b>Manufactured by:</b>          MSN Laboratories Private Limited          Telangana – 509 228,          INDIA</p> <p><b>Distributed by:</b>          Novadoz Pharmaceuticals LLC          Piscataway, NJ 08854-3714</p>