Tamoxifen Monotherapy

INDICATIONS FOR USE:

INDICATION	ICD10	Regimen Code	HSE approved Reimbursement Status*
Adjuvant treatment of oestrogen receptor positive breast cancer in pre- or post-menopausal women.	C50	00253a	N/A
Treatment of oestrogen receptor positive advanced breast cancer in pre- or post-menopausal women	C50	00253b	N/A

* This applies to post 2012 indications

TREATMENT:

The starting dose of the drugs detailed below may be adjusted downward by the prescribing clinician, using their independent medical judgement, to consider each patient's individual clinical circumstances.

Tamoxifen is administered orally once daily continuously during treatment. Duration of treatment will be determined by the prescribing Consultant and depends on disease progression or unacceptable toxicity.

Drug	Dose	Route	Cycle
Tamoxifen	20 mg daily	PO	Continuous for specified duration or until disease progression or unacceptable toxicity
Tablet should be swallowed whole. Can be taken with food or on an empty stomach with a glass of water. If nausea develops, tamoxifen may be taken with or after food or at night. If patient vomits within a few hours of taking the drug, do not repeat the dose.			
Missed doses should not be replaced, normal dosing should be resumed at the next scheduled daily dose. Tamoxifen is commonly available as 10mg and 20mg tablets.			

ELIGIBILITY:

- Indications as above

EXCLUSIONS:

- Hypersensitivity to tamoxifen or any of the excipients
- Pregnancy
- Breastfeeding
- Patients with a history of significant thromboembolic disease

PRESCRIPTIVE AUTHORITY:

Medical oncologist or General Practitioner under direction of plan written by medical oncologist.

TESTS:

Baseline tests:

- FBC, renal and liver profile

Regular tests:

- Ophthalmology if clinically indicated
- INR as clinically indicated
- Repeat LFTs as clinically indicated

Disease monitoring:

- Metastatic disease: Disease monitoring/assessment should be in line with the patient's treatment plan and any other test/s as directed by the supervising Consultant.
- Adjuvant treatment: No routine tests required

DOSE MODIFICATIONS:

- Any dose modification should be discussed with a Consultant.
- Intolerant or serious complications during tamoxifen therapy. (Note: Post-menopausal patients may be switched to aromatase inhibitor therapy for a total of 5 years of adjuvant hormonal therapy).

Renal and Hepatic Impairment:

Table 1: Dose modification of Tamoxifen in renal and hepatic impairment

Renal Impairment	Hepatic Impairment
No need for dose adjustment is expected Haemodialysis: No need for dose adjustment is expected	Mild/ moderate: no dose adjustment is needed Severe: not recommended
Recommendations as per Giraud et al 2023	

SUPPORTIVE CARE:

EMETOGENIC POTENTIAL:

- As outlined in NCCP Classification Document for Systemic Anti-Cancer Therapy (SACT) Induced Nausea and Vomiting- Available on the NCCP website

Tamoxifen: Minimal (**Refer to local policy).**

For information:
Within NCIS regimens, antiemetics have been standardised by Medical Oncologists and Haemato-oncologists and information is available in the following documents:

- NCCP Supportive Care Antiemetic Medicines for **Inclusion in NCIS** (Medical Oncology) - Available on the NCCP website
- NCCP Supportive Care Antiemetic Medicines for **Inclusion in NCIS** (Haemato-oncology) - Available on the NCCP website

PREMEDICATIONS: Not usually required

OTHER SUPPORTIVE CARE: None usually required

ADVERSE EFFECTS:

- Please refer to the relevant Summary of Product Characteristics (SmPC) for details.

REGIMEN SPECIFIC COMPLICATIONS:

- **Thromboembolism:** Tamoxifen is associated with an increased risk of thromboembolism that is comparable to estrogen replacement therapy.
- **Endometrial Cancer:** An increased incidence in endometrial changes have been reported in association with tamoxifen. Annual gynecological examinations are recommended. Pelvic complaints, such as unusual vaginal bleeding, require prompt evaluation.
- **Myelosuppression:** Mild myelosuppression with transient thrombocytopenia may occur rarely. The association with tamoxifen is uncertain.
- **Ocular Toxicity:** Ocular toxicity is rare and may occur after only a few weeks of therapy, although it is more common with prolonged treatment. Ophthalmologic examination is recommended if visual disturbances occur.
- **Hepatotoxicity:** While hepatotoxicity is rare and usually presents as elevated hepatic enzymes, more serious liver abnormalities have been reported.
- **Ovulation Induction:** Tamoxifen may induce ovulation in pre- and peri-menopausal women. Barrier forms of contraception are recommended.
- **Hyperlipidemia:** Elevations in cholesterol and triglycerides may occur in patients with pre-existing hyperlipidemias.

DRUG INTERACTIONS:

- Current SmPC and drug interaction databases should be consulted for information.

REFERENCES:

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2. Davies C, Godwin J, Gray R, et al. Relevance of breast cancer hormone receptors and other factors to the efficacy of adjuvant tamoxifen: patient-level meta-analysis of randomised trials. Lancet 2011;378(9793):771-784.
3. Davies C, Pan H, Godwin J, et al. Long-term effects of continuing adjuvant tamoxifen to 10 years versus stopping at 5 years after diagnosis of oestrogen receptor-positive breast cancer: ATLAS, a randomised trial. Lancet 2013;381(9869):805-16.
4. Delozier T, Switsers O, Genot JY et al. Delayed adjuvant tamoxifen: ten-year results of a collaborative randomized controlled trial in early breast cancer (TAM-02 trial). Ann Oncol 2000;11:515-9.
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6. Muss HB, Case LD, Atkins JN, et al. Tamoxifen versus high-dose oral medroxyprogesterone acetate as initial endocrine therapy for patients with metastatic breast cancer: a Piedmont Oncology Association

study. J Clin Oncol 1994;12(8):1630-1638.Giraud E L, Lijster B D, et al. Dose recommendations for anticancer drugs in patients with renal or hepatic impairment: an update. Available at: https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(23)00216-4/fulltext

7. NCCP Classification Document for Systemic Anti-Cancer Therapy (SACT) Induced Nausea and Vomiting. V6 2025. Available at: https://www.hse.ie/eng/services/list/5/cancer/profinfo/chemoprotocols/nccp-classification-document-for-systemic-anti-cancer-therapy-sact-induced-nausea-and-vomiting.pdf
8. Tamoxifen Summary of Product Characteristics. Accessed 23/09/2025. Last updated 03/04/2025. Available at: https://assets.hpra.ie/products/Human/17076/Licence_PA0577-207-001_31052024150315.pdf

Version	Date	Amendment	Approved By
1	1/11/2014		Prof Maccon Keane
2	20/10/2016	Reviewed no changes	Prof Maccon Keane
3	26/11/2018	Updated with new NCCP regimen template and clarified treatment duration	Prof Maccon Keane
4	10/11/2020	Reviewed	Prof Maccon Keane
5	19/12/2025	Reviewed.Updated exclusions and regular testing sections. Added renal and hepatic dose modifications table (Table 1). Updated in line with NCCP standardisation.	Prof Maccon Keane

Comments and feedback welcome at oncologydrugs@cancercontrol.ie.