Tamoxifen Monotherapy

INDICATIONS FOR USE:

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

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 patients 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	Diluent & Rate	Cycle
Tamoxifen	20 mg daily	PO	NA	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				

ELIGIBILITY:

- Indications as above

EXCLUSIONS:

- Hypersensitivity to tamoxifen or any of the excipients.
- Hormone receptor-negative.
- Pregnancy
- 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:

- None unless 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).

SUPPORTIVE CARE:

EMETOGENIC POTENTIAL: Minimal Risk (**Refer to local policy).**

PREMEDICATIONS: Not usually required

OTHER SUPPORTIVE CARE:
Not usually required

ADVERSE EFFECTS / REGIMEN SPECIFIC COMPLICATIONS

The adverse effects listed are not exhaustive. Please refer to the relevant Summary of Product Characteristics for full details.

- **Myelosuppression:** Mild myelosuppression with transient thrombocytopenia may occur rarely. The association with tamoxifen is uncertain.
- **Endometrial Cancer:** Annual gynecological examinations are recommended. Pelvic complaints, such as unusual vaginal bleeding, require prompt evaluation.
- **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.
- **Thromboembolism:** Tamoxifen is associated with an increased risk of thromboembolism that is comparable to estrogen replacement therapy.
- **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 drug interaction databases should be consulted for more information.
- Medications that inhibit CYP2D6 (e.g., paroxetine, fluoxetine, quinidine, bupropion) should be avoided as they may decrease the efficacy of tamoxifen.
  Co-administration of tamoxifen and aromatase inhibitors should be avoided.

ATC CODE:

Tamoxifen - L02BA01

REFERENCES:

1. Early Breast Cancer Trialists' Collaborative Group. Effects of chemotherapy and hormonal therapy for early breast cancer on recurrence and 15-year survival: an overview of the randomised trials. Lancet. 2005;365(9472):1687-1717.
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.
5. Eisen A, Trudeau M, Shelley W, et al. Aromatase inhibitors in adjuvant therapy for hormone receptor positive breast cancer: a systematic review. Cancer Treat Rev 2008;34(2):157-174.
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.
7. Novaldex D ® Summary of Product Characteristics Accessed Oct 2020. Last updated Oct 2020 Available at https://www.hpra.ie/img/uploaded/swedocuments/Licence_PA1019-014-001_12102020151102.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

Comments and feedback welcome at oncologydrugs@cancercontrol.ie.