Tamoxifen Monotherapy

**INDICATIONS FOR USE:**

<table>
<thead>
<tr>
<th>INDICATION</th>
<th>ICD10</th>
<th>Regimen Code</th>
<th>*Reimbursement Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adjuvant treatment of oestrogen receptor positive breast cancer in pre- or post-menopausal women.</td>
<td>C50</td>
<td>00253a</td>
<td>CDS</td>
</tr>
<tr>
<td>Treatment of oestrogen receptor positive advanced breast cancer in pre- or post-menopausal women</td>
<td>C50</td>
<td>00253b</td>
<td>CDS</td>
</tr>
</tbody>
</table>

*If the reimbursement status is not defined, the indication has yet to be assessed through the formal HSE reimbursement process.

**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.**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>Route</th>
<th>Diluent &amp; Rate</th>
<th>Cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tamoxifen</td>
<td>20 mg daily</td>
<td>PO</td>
<td>NA</td>
<td>Continuous for specified duration or until disease progression or unacceptable toxicity</td>
</tr>
</tbody>
</table>

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

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The information contained in this document is a statement of consensus of NCCP and ISMO or IHS professionals regarding their views of currently accepted approaches to treatment. Any clinician seeking to apply or consult these documents is expected to use independent medical judgement in the context of individual clinical circumstances to determine any patient's care or treatment. Use of these documents is the responsibility of the prescribing clinician. and is subject to HSE’s terms of use available at [http://www.hse.ie/eng/TermsandConditions](http://www.hse.ie/eng/TermsandConditions)

This information is valid only on the day of printing, for any updates please check [www.hse.ie/NCCPchemoregimens](http://www.hse.ie/NCCPchemoregimens)
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:** Elevation 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.
NCCP Chemotherapy Regimen

**ATC CODE:**
Tamoxifen - L02BA01

**REFERENCES:**

<table>
<thead>
<tr>
<th>Version</th>
<th>Date</th>
<th>Amendment</th>
<th>Approved By</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1/11/2014</td>
<td></td>
<td>Prof Maccon Keane</td>
</tr>
<tr>
<td>2</td>
<td>20/10/2016</td>
<td>Reviewed no changes</td>
<td>Prof Maccon Keane</td>
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<tr>
<td>3</td>
<td>26/11/2018</td>
<td>Updated with new NCCP regimen template and clarified treatment duration</td>
<td>Prof Maccon Keane</td>
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</table>

Comments and feedback welcome at oncologydrugs@cancercontrol.ie.

1 ODMS – Oncology Drug Management System
CDS – Community Drug Schemes (CDS) including the High Tech arrangements of the PCRS community drug schemes
Further details on the Cancer Drug Management Programme is available at; http://www.hse.ie/eng/services/list/5/cancer/proinfo/medonc/cdmp/