Anastrozole Monotherapy

INDICATIONS FOR USE:

INDICATION	ICD10	Regimen Code	HSE approved reimbursement status*
Treatment of hormone receptor positive locally advanced or metastatic breast cancer in post-menopausal women.	C50	254a	N/A
Adjuvant treatment of postmenopausal women with hormone receptor positive invasive early breast cancer	C50	254b	N/A
Extended adjuvant treatment of hormone-dependent-invasive breast cancer in postmenopausal women who have received 2 to 3 years of adjuvant tamoxifen.	C50	254c	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 patients individual clinical circumstances.

Anastrozole 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.

Day	Drug	Dose	Route	Cycle
1	Anastrozole	1mg daily	PO	Continuous daily as indicated until disease progression or unacceptable toxicity.
Daily oral supplement of calcium and Vit D are recommended for duration of therapy.				
Tablet should be swallowed whole. Can be taken with food or on an empty stomach with a glass of water If nausea develops, anastrozole 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
- Contraindications to tamoxifen or intolerant of tamoxifen.

CAUTIONS:

- Severe renal impairment
- Moderate to severe hepatic impairment

EXCLUSIONS:

- Hypersensitivity to anastrozole or any of the excipients.
- Pregnancy
- Breastfeeding

PRESCRIPTIVE AUTHORITY:

The treatment plan must be initiated by a Consultant Medical Oncologist or General Practitioner under the direction of plan written by medical oncologist

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 responsibly of the prescribing clinician. and is subject to HSE's terms of use available at http://www.hse.ie/eng/Disclaimer

This information is valid only on the day of printing, for any updates please check www.hse.ie/NCCPSACTregimens

TESTS:

Baseline tests:

- FBC, U&Es, LFTs.Check FSH, LH, oestradiol levels if less than 55 and prior hysterectomy or uncertain menopausal status due to young age or other factors

Regular tests:

- Women with osteoporosis or at risk of osteoporosis, should have their bone mineral density formally assessed at the commencement of treatment and at regular intervals thereafter
- Lipid profile as clinically indicated

Disease monitoring:

Disease monitoring should be in line with the patient's treatment plan and any other test/s as directed by the supervising Consultant.

DOSE MODIFICATIONS:

- No recommended dose modifications.
- Any dose modification should be discussed with a Consultant.

Renal and Hepatic Impairment:

Table 2: Dose modification of Anastrozole in renal and hepatic impairment

Renal Impairment	Hepatic Impairment
Renal impairment: No dose adjustment is needed Haemodialysis: no dose adjustment is needed	Mild and 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

Anastrozole: 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

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 responsibly of the prescribing clinician. and is subject to HSE's terms of use available at http://www.hse.ie/eng/Disclaimer

This information is valid only on the day of printing, for any updates please check www.hse.ie/NCCPSACTregimens

PREMEDICATIONS:

None usually required

OTHER SUPPORTIVE CARE:

Bone density: The long-term effects of aromatase inhibitors on bone density in adjuvant therapy patients are unknown. Supplementation with calcium and vitamin D and regular weight bearing exercise is recommended. A bisphosphonate should be considered if clinically indicated. Caution in patients with an already established diagnosis of clinically significant osteoporosis.

ADVERSE EFFECTS:

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

REGIMEN SPECIFIC COMPLICATIONS:

- **Hepatic dysfunction**: Aromatase inhibitors are considered safe in mild-to-moderate hepatic dysfunction but have not been studied in severe hepatic dysfunction.

DRUG INTERACTIONS:

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

REFERENCES:

1. Cuzick J, Sestak I et al. Effect of anastrozole and tamoxifen as adjuvant treatment for early-stage breast cancer: 10-year analysis of the ATAC trial. Lancet Oncol 2010; 11:1135-1141.
2. Eisen, A., M. Trudeau, W. Shelley, et al. Aromatase inhibitors in adjuvant therapy for hormone receptor positive breast cancer: a systematic review. Cancer Treat Rev 2008;34(2):157-174.
3. Jonat W, Gnant M, Boccardo F et al. Effectiveness of switching from adjuvant tamoxifen to anastrozole in postmenopausal women with hormone-sensitive early-stage breast cancer: a meta-analysis. Lancet Oncol. 2006;7:991-996.
4. Jakesz R, Jonat W. et al. Switching of postmenopausal women with endocrine-responsive early breast cancer to anastrozole after 2 years' adjuvant tamoxifen: combined results of ABCSG trial 8 and ARNO 95 trial. Lancet 2005; 366:455-462.
5. Howell A, Cuzick J et al. Results of the ATAC (Arimidex, Tamoxifen, alone or in combination) trial after completion of 5 years' adjuvant treatment for breast cancer. Lancet 2005;365(9453): 60-2
6. Bonneterre J, Buzdar A. et al. Anastrozole is superior to tamoxifen as first-line therapy in hormone receptor positive advanced breast carcinoma. Cancer 2001:92;2247-2258**.**
7. 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://pubmed.ncbi.nlm.nih.gov/37269847/
8. Anastrozole 1mg tablets Summary of Product Characteristics. Accessed 30/09/2025. Last updated 25/07/2025. Available at: https://assets.hpra.ie/products/Human/20912/Licence_PA0749-028-001_25072025123349.pdf

Version	Date	Amendment	Approved By
1	1/11/2014		Prof Maccon Keane
2	16/11/2016	Reviewed-clarified wording of indications	Prof Maccon Keane
3	26/11/2018	Updated with new NCCP regimen template. Clarified treatment duration	Prof Maccon Keane

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 responsibly of the prescribing clinician. and is subject to HSE's terms of use available at http://www.hse.ie/eng/Disclaimer

This information is valid only on the day of printing, for any updates please check www.hse.ie/NCCPSACTregimens

4	10/11/2020	Reviewed	Prof Maccon Keane
5	19/12/2025	Reviewed. Updated exclusions section. Addition of cautions section. Updated regular testing section. Update to other supportive care section. Regimen updated in line with NCCP standardisation.	Prof Maccon Keane

Comments and feedback welcome at oncologydrugs@cancercontrol.ie.

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 responsibly of the prescribing clinician. and is subject to HSE's terms of use available at http://www.hse.ie/eng/Disclaimer

This information is valid only on the day of printing, for any updates please check www.hse.ie/NCCPSACTregimens