

## DORSET CANCER NETWORK BREAST SITE SPECIFIC GROUP

### Shared Care Guideline for the use of adjuvant Letrozole (Femara) in the Management of Early Breast Cancer

#### INTRODUCTION

This shared care guideline has been developed to support the transfer of responsibility for prescribing Letrozole from secondary to primary care.

It has been developed specifically for use in post-menopausal women who have been initiated on Letrozole by a consultant as adjuvant or neo-adjuvant treatment for breast cancer.

#### MANAGEMENT OF BREAST CANCER

Breast cancer is the commonest female malignancy with a 1:9 lifetime risk of developing the disease. Many of these women will require hormone therapy for early disease.

Adjuvant treatment for breast cancer refers to treatment following potentially curative surgery in order to remove micro-metastatic disease in an attempt to prevent recurrence.

If recurrence of disease is identified or suspected, the patient should be referred immediately to hospital for further investigation.

Neo-adjuvant treatment refers to pre-surgical treatment for patients with advanced local disease to down-stage prior to surgery or for those patients unfit for surgical intervention.

#### INDICATIONS FOR THE USE OF LETROZOLE

Letrozole is a reversible, non-steroidal aromatase inhibitor, inhibiting the conversion of androgens to oestrogens.

It is licensed and recommended for:

- neo-adjuvant use
- adjuvant treatment of postmenopausal women with oestrogen receptor positive invasive early breast cancer for women who have already received 5 years of adjuvant Tamoxifen therapy.

It is also licensed for primary adjuvant therapy and may be used in this indication for patients unsuitable for anastrozole or considered at high risk of early relapse with metastatic disease (duration = 5years of treatment).

#### Dose

The recommended dose is 2.5mg orally **once** daily.

Following standard adjuvant Tamoxifen therapy, treatment with Letrozole should continue for five years or until tumour progression is evident.

Neo-adjuvant treatment should continue until surgery, or if unfit for surgery, until progression occurs.

#### SAFETY ISSUES

#### Contra-indications

The summary of product characteristics includes the following contra-indications:

- pre-menopausal women;
- pregnant or lactating women;
- patients with severe hepatic impairment;

#### Special warnings/precautions

The Summary of Product Characteristics includes the following:

- where clinically appropriate, post-menopausal status should be ascertained by assessment of LH, FSH and oestradiol levels;
- **care** in driving or operating machinery;
- Women with osteoporosis or at risk of osteoporosis should have bone mineral density assessed at the start of therapy and at regular intervals.

#### Side-effects

Side effects are usually mild to moderate. The most frequently reported adverse reactions were hot flushes, nausea and fatigue/asthenia. Other common adverse events include musculoskeletal disorders (arthralgia/myalgia), anorexia or weight gain, GI upset, headache, hair thinning, depression and rash. For less common adverse effects please refer to the Summary of Product Characteristics.

#### Drug interactions

- should **not** be co-administered with oestrogen-containing therapies (action negated);

#### **RESPONSIBILITIES OF THE GENERAL PRACTITIONER**

1. Provision of general care and advice to the patient and her family/carers.
2. Reporting any adverse events to the consultant.
3. Reporting any suspected disease recurrence to the consultant.
4. Providing the patient with repeat prescriptions for Letrozole and calcium + vitamin D (plus bisphosphonates if requested by Consultant).

#### **RESPONSIBILITIES OF THE CONSULTANT**

1. To assess the patient, determine a management plan in consultation with the patient and their GP.
2. To initiate treatment with Letrozole. **A minimum of 28 day's treatment should be prescribed by the hospital consultant.**
3. To seek agreement from the patient's GP to transfer responsibility for prescribing. **Note:** Treatment should **continue to be prescribed by the hospital consultant** until information has been received by the GP.
4. Assess the continued appropriateness of Letrozole and notify the GP of any changes or additions to prescribed therapy.

5. Report any serious adverse events associated with Letrozole via the yellow card system, and assess any reports from the GP regarding adverse events/progression.
6. To assess bone health and instigate surveillance and treatment in accordance with national guidelines.
7. Ensure that all other medical professionals in the shared care team are kept informed of any changes in the patient's circumstances.

#### **RESPONSIBILITIES OF THE BREAST NURSE**

1. Talking with patients at the clinics to establish their overall well being.
2. Informing other members of the shared care team of any information obtained from the patient that the patient feels important.
3. Providing support and care to patients and their families/carers.
4. Advising patients on sources of information about their disease.

#### **RESPONSIBILITIES OF THE COMMUNITY PHARMACIST**

1. To provide support and advice to the patient and/or family regarding concordance, adverse effects and over the counter therapies.
2. To monitor concordance with therapy and refer the patient to their GP if any concern arises.

#### **COST**

2.5mg daily, 28 days treatment £83.16 (excluding VAT; BNF 51st edition, March 2006)

#### **CONTACTS**

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