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SHARED CARE GUIDELINE

FULVESTRANT (Faslodex®)

Contact Details	Patient Identifier
Name: _____	Surname: _____
Location: _____	Forenames: _____
Date: _____	NHS Number: _____
Phone No. _____	Date of Birth: _____

Introduction	**Indication:** Fulvestrant is indicated for the treatment of postmenopausal women with oestrogen receptor positive, locally advanced or metastatic breast cancer for disease relapse on or after adjuvant anti-oestrogen therapy or disease progression on therapy with an anti-oestrogen. **Background:** Patients who have oestrogen positive breast cancer are currently treated with either tamoxifen or an aromatase inhibitor. When the disease progresses, treatment options are limited but fulvestrant is an option. Fulvestrant is an oestrogen receptor antagonist and binds to oestrogen receptors in a competitive manner with an affinity comparable with that of oestradiol. Fulvestrant blocks the trophic actions of oestrogens without itself having any partial agonist (oestrogen-like) activity. The mode of action is associated with down-regulation of oestrogen receptor (ER) protein. Clinical trials in postmenopausal women with primary breast cancer have shown that fulvestrant significantly down-regulates ER protein in ER positive tumours compared with placebo. There was also a significant decrease in progesterone receptor expression consistent with a lack of intrinsic oestrogen agonist effects.
Purpose	These guidelines aim to provide a model framework for the prescribing of fulvestrant by GPs, and to set out the associated responsibilities of GPs and hospital specialists who enter into shared care arrangements for patients who are treated with fulvestrant.
Scope	Fulvestrant therapy should only be used as a fourth line endocrine therapy, where patients have progressed following treatment with tamoxifen, anastrozole/letrozole and exemestane. The treatment algorithm attached gives an overview of the options available for treatment of postmenopausal women with advanced breast cancer.
Dose & Administration	The recommended dose is 500mg into gluteal muscle at intervals of 1 month, with an additional 500mg given two weeks after the first dose. Fulvestrant should be administered as two consecutive 5ml injections by slow intramuscular injection (1-2 minutes/injection), one in each buttock. The injection is supplied as a pre-filled syringe. A detailed description of injection technique is available in the fulvestrant SPC which can be accessed via www.medicines.org.uk
Secondary Care Responsibilities	**1.** Assess the patient and establishing a need for fulvestrant**.** **2.** Provide information for the patient, including adverse effects, obtaining consent and initiating treatment. **3.** Contact the GP to invite shared care for the patient. 4. Inform the GP of the dose and frequency of fulvestrant together with a clinical summary.

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	5. Administer the first dose of fulvestrant. 6. Assess the patient's tolerability to the first dose. 7. Assess the continued appropriateness for fulvestrant on a 3 monthly basis. 8. Review any concerns regarding disease progression from the GP within 2 weeks.
Primary Care Responsibilities	1. Assessment of continued well being of the patient. 2. Monitoring toxicity and reporting adverse events to the consultant. 3. Providing the patient with repeat prescriptions for fulvestrant injection every 4 weeks, and arranging its administration. 4. Referring for review if there are signs of disease progression. 5. Ensuring that all other medical professionals in the shared care team are kept informed of any changes in the patient's circumstances.
Ancillary products /apparatus which may need to be prescribed by a GP	Fulvestrant is available in a pack of two pre-filled syringes, each containing 250mg in a 5ml solution, two safety needles (SafetyGlide®) are also provided. Appropriate sharps disposal is needed. *The injection must be stored in a fridge.*
Monitoring Required in Primary Care	None, other than for tolerability.
Patient Information & Responsibilities	The breast care team will provide the patient with information about their treatment on starting the medicine. Patients / carers will be counselled to report side effects to any member of the health care team.
Adverse Effects	Fulvestrant is well tolerated with a side effect profile similar to anastrazole. It demonstrates a significantly reduced incidence of joint disorders (including arthralgia, arthrosis and arthritis) compared with anastrozole. The most commonly reported adverse reactions are: Hot flushes, nausea, vomiting, diarrhoea, anorexia, headache, back pain, rash, asthenia, venous thromboembolism, injection-site reactions, urinary tract infections. Less commonly, vaginal haemorrhage, vaginal candidiasis, leucorrhoea, hypersensitivity reactions including angioedema, urticaria. Always consult the latest version of the Summary of Product Characteristics (SPC) at www.medicines.org.uk for full details.
Common Drug Interactions	None known.
Cautions & Contraindications	Known hypersensitivity to the active substance or to any of the excipients, pregnancy and in breast-feeding, severe hepatic impairment. It should be used with caution in mild to moderate hepatic impairment. Patients with mild renal impairment should be treated with fulvestrant with caution and safety has not been assessed in patients with renal impairment (CrCl <30ml/minute) so use is not advised in this group. As it is an intramuscular injection it should be used with caution in patients with clotting abnormalities.

This guidance does not replace the SPC's, which should be read in conjunction with this guidance.

TREATMENT OPTIONS