Effective Shared Care Agreement (ESCA)

Ulipristal acetate 5mg tablets (Esmya)

ESCA: For 3 months pre-operative treatment of moderate to severe symptoms of uterine fibroids (1 course)

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of ulipristal acetate (Esmya) for pre-operative treatment of moderate to severe symptoms of uterine fibroids can be shared between the specialist and general practitioner (GP). You are **invited** to participate however, if you do not feel confident to undertake this role, then you are under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist.

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care will be explained to the patient by the specialist initiating treatment. It is important that patients are consulted about treatment and are in agreement with it. Patients with pre-operative treatment of moderate to severe symptoms of uterine fibroids are usually under regular specialist follow-up, which provides an opportunity to discuss drug therapy.

The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

RESPONSIBILITIES and ROLES

Specialist responsibilities
1. Confirm the diagnosis of pre-operative treatment of moderate to severe symptoms of uterine fibroids.
2. Discuss the potential benefits, treatment side effects, and possible drug interactions with the patient.
3. Ask the GP whether he or she is willing to participate in shared care before initiating therapy so that appropriate follow on prescribing arrangements can be made.
4. Do baseline monitoring prior to initiation of ulipristal acetate (Esmya).
5. Initiate treatment (during the first week of a menstrual cycle) with ulipristal acetate for the three month treatment course.
6. Ensure that the patient (or patient's representative) understands that treatment is only available for 3 months as a pre-operative treatment and that there is no scope to extend this treatment period.
7. Review the patient's condition and monitor response to treatment regularly.
8. A written summary to be sent promptly to the GP i.e. within 10 working days of a hospital outpatient review or inpatient stay.
9. Report any adverse events to the MHRA.
10. Ensure clear backup arrangements exist for GPs, for advice and support (Please complete details below).

General Practitioner responsibilities						
1. Reply to the request for shared care as soon as practicable i.e. within 10 working days.						
2. Prescribe ulipristal acetate (Esmya) at the dose recommended and for a maximum of 2 months until surgery.						
3. In the patient's notes, using the appropriate Read Code listed below, denote that the patient is receiving treatment under a shared care agreement						
GP Prescribing System	**Read Code**	**Description**		**GP Prescribing System**	**Read Code**	**Description**
EMIS and Vision	8BM5.00	Shared care prescribing		SystmOne	XaB58	Shared care
4. Monitor patient's response to treatment; make dosage adjustments if agreed with specialist						
5. Report to and seek advice from the specialist or clinical nurse specialist on any aspect of patient care that is of concern to the GP, patient or carer and may affect treatment. e.g. Advise if symptoms continue or if in female patients menstruation fails to be suppressed after 2 months treatment.						
6. Refer back to specialist if condition deteriorates.						
7. Report any adverse events to specialist and MHRA.						
8. Stop treatment on advice of specialist.						

Patient's role
1. Consent to treatment with ulipristal acetate for a maximum period of 3 months.
2. Report to the specialist, clinical nurse specialist or GP if he or she does not have a clear understanding of the treatment.
3. Share any concerns in relation to treatment with ulipristal acetate (Esmya) with the specialist, clinical nurse specialist or GP.
4. Report any adverse effects to the specialist or GP whilst taking ulipristal acetate (Esmya).
5. Attend regular outpatient appointments with the specialist

BACK-UP ADVICE AND SUPPORT

Trust	Contact details	Telephone No.	Email address:
	Consultant:-		
	Specialist Nurse		

Based on MTRAC template
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Interface Lead Pharmacist
Birmingham CrossCity CCG

SUPPORTING INFORMATION

Indication	For pre-operative treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age.	
Dosage and Administration	The treatment consists of one tablet of 5 mg to be taken orally once daily for up to 3 months. Treatments should always be started during the first week of menstruation. If a patient misses a dose, the patient should take ulipristal acetate as soon as possible. If the dose was missed by more than 12 hours, the patient should not take the missed dose and simply resume the usual dosing schedule.	
Renal Impairment	Mild	No dose adjustment required
	Moderate	
	Severe	Not recommended
Hepatic impairment	Mild	No dose adjustment required
	Moderate	Monitor patients closely
	Severe	
Contra-indications / Special precautions	**Contraindications** Hypersensitivity to the active substance or to any of the excipients listed Pregnancy and breastfeeding. Genital bleeding of unknown aetiology or for reasons other than uterine fibroids. Uterine, cervical, ovarian or breast cancer. **Cautions** Ulipristal acetate should only be prescribed after careful diagnosis. Pregnancy should be precluded prior to treatment. <u>Contraception</u> Concomitant use of progestogen-only pills, a progestogen-releasing intrauterine device or combined oral contraceptive pills is not recommended. Although a majority of women taking a therapeutic dose of ulipristal acetate have anovulation, a non hormonal contraceptive method is recommended during treatment. <u>Renal impairment</u> Renal impairment is not expected to significantly alter the elimination of ulipristal acetate. In the absence of specific studies, ulipristal acetate is not recommended for patients with severe renal impairment unless the patient is closely monitored. <u>Hepatic impairment</u> There is no therapeutic experience with ulipristal acetate in patients with hepatic impairment. Hepatic impairment is expected to alter the elimination of ulipristal acetate, resulting in increased exposure. This is considered not to be clinically relevant for patients with mildly impaired liver function. Ulipristal acetate is not recommended for use in patients with moderate or severe hepatic impairement unless the patient is closely monitored. <u>Concomitant treatments</u> Co-administration of moderate (e.g. erythromycin, grapefruit juice, verapamil) or potent (e.g. ketoconazole, ritonavir, nefazodone, itraconazole, telithromycin, clarithromycin) CYP3A4 inhibitors and ulipristal acetate is not recommended Concomitant use of ulipristal acetate and potent CYP3A4 inducers (e.g. rifampicin, rifabutin, carbamazepine, oxcarbazepine, phenytoin, fosphenytoin, phenobarbital, primidone, St John´s wort, efavirenz, nevirapine, long term use of ritonavir) is not recommended. <u>Asthma patients</u> Use in women with severe asthma insufficiently controlled by oral glucocorticoids is not recommended. <u>Endometrial changes</u> Ulipristal acetate has a specific pharmacodynamic action on the endometrium. Increase in thickness of the endometrium may occur. If the endometrial thickening persists beyond 3 months following the end of treatment and return of menstruations, this may need to be investigated as per usual clinical practice to exclude underlying conditions. Changes in the histology of the endometrium may be observed in patients treated with ulipristal acetate. These changes are reversible after treatment cessation. These histological changes are denoted as “Progesterone Receptor Modulator Associated Endometrial Changes” (PAEC) and should not be mistaken for endometrial hyperplasia. <u>BSSE Health economy</u> - Ono treatment course is recommended. The treatment course should not exceed 3 months as the risk of adverse impact on the endometrium is unknown if treatment is continued. <u>Bleeding pattern</u> Patients should be informed that treatment with ulipristal acetate usually leads to a significant reduction in menstrual blood loss or amenorrhea within the first 10 days of treatment. Should the excessive bleeding persist, patients should notify their specialist/clinical nurse specialist/GP. Menstrual periods will generally return within 4 weeks after the end of the treatment course.	
Side Effects	Very common	Amenorrhea, endometrial thickening
	Common	Headache, vertigo, abdominal pain, nausea, acne, hyperhidrosis, musculoskeletal pain, uterine haemorrhage, hot flush, pelvic pain, ovarian cyst, breast tenderness/pain, oedema, fatigue, blood cholesterol increased

Monitoring	Renal function Liver function
Drug interactions (highlighted interaction are the significant ones)	**Ulipristal** has the following interaction information:

Carbamazepine	manufacturer of ulipristal advises avoid concomitant use with carbamazepine (contraceptive effect of ulipristal possibly reduced)
Clarithromycin	manufacturer of *low-dose* ulipristal advises avoid concomitant use with clarithromycin
Dabigatran	manufacturer of ulipristal advises give dabigatran at least 1.5 hours before or after ulipristal
Digoxin	manufacturer of ulipristal advises give digoxin at least 1.5 hours before or after ulipristal
Erythromycin	plasma concentration of *low-dose* ulipristal increased by erythromycin —manufacturer of *low-dose* ulipristal advises avoid concomitant use**. Note:** Interactions do not apply to small amounts of erythromycin used topically
Fexofenadine	manufacturer of ulipristal advises give fexofenadine at least 1.5 hours before or after ulipristal
Fosphenytoin	manufacturer of ulipristal advises avoid concomitant use with fosphenytoin (contraceptive effect of ulipristal possibly reduced)
Grapefruit Juice	manufacturer of *low-dose* ulipristal advises avoid concomitant use with grapefruit juice
Itraconazole	manufacturer of ulipristal advises avoid concomitant use with itraconazole
Ketoconazole	plasma concentration of *low-dose* ulipristal increased byketoconazole —manufacturer of *low-dose* ulipristal advises avoid concomitant use
Phenobarbital	manufacturer of ulipristal advises avoid concomitant use with phenobarbital (contraceptive effect of ulipristal possibly reduced)
Phenytoin	manufacturer of ulipristal advises avoid concomitant use with phenytoin (contraceptive effect of ulipristal possibly reduced)
Primidone	manufacturer of ulipristal advises avoid concomitant use with primidone (contraceptive effect of ulipristal possibly reduced)
Progestogens	ulipristal possibly reduces contraceptive effect of progestogens
Rifampicin	manufacturer of ulipristal advises avoid concomitant use with rifampicin (contraceptive effect of ulipristal possibly reduced)
Ritonavir	manufacturer of ulipristal advises avoid concomitant use with ritonavir (contraceptive effect of ulipristal possibly reduced)
St John's Wort	manufacturer of ulipristal advises avoid concomitant use with St John's wort (contraceptive effect of ulipristal possibly reduced)
Telithromycin	manufacturer of *low-dose* ulipristal advises avoid concomitant use with telithromycin
Verapamil	manufacturer of *low-dose* ulipristal advises avoid concomitant use with verapamil

References

Esmya SmPC
Ulipristal acetate BNF

I agree to participate in this shared care agreement for the treatment of the below named patient with ulipristal acetate (Esmya) for pre-operative treatment of moderate to severe symptoms of uterine

General Practitioner
Name (please print)_____Signature _____Date_____

Hospital Specialist/Consultant
Name (please print)_____Signature_____Date_____

Patient's name	Date of birth	Sex	Home Address	Hospital Number
				NHS Number

Please keep a copy of this agreement for your own records and forward the original to the above named Consultant at: