

Greater Manchester Interface Prescribing Group Shared Care Template

Shared Care Guideline for LEUPRORELIN (PROSTAP) for the treatment of endometriosis, endometrial thinning prior to surgery and reduction of uterine fibroids		This document replaces GLTW 07 issued in January 2007 by GMMMG
Author(s)/Originator(s): Women & Children's division Drug & Therapeutics committee (Pennine Acute Hospitals NHS Trust)		To be read in conjunction with the following documents: Summary of Product characteristics BNF
Date approved by Commissioners: 11/11/11	Review Date: 11/11/14	

Please complete all sections

1. Licensed Indications	Leuprorelin is licensed for several indications, but this document only refers to the management of endometriosis, endometrial thinning prior to surgery and reduction in size of uterine fibroids.	
2. Therapeutic use & background	Leuprorelin promotes the internalisation of gonadotrophin-releasing hormone (GnRH) receptors in the pituitary gland. Initially an increase in Gn output with increased circulating sex hormone levels is observed but within four weeks of therapy the pituitary is devoid of receptors and sex hormones fall.	
3. Contraindications (please note this does not replace the SPC or BNF and should be read in conjunction with it).	Hypersensitivity to any of the ingredients or to synthetic Gn-RH or Gn-RH derivatives. Contraindicated in women who are or may become pregnant while receiving the drug. Should not be used in women who are breastfeeding or have undiagnosed abnormal vaginal bleeding.	
4. Prescribing in pregnancy and lactation	See section 3	
5. Dosage regimen for continuing care	Route of administration	Subcutaneous or intramuscular injection
	Preparations available 3.75mg vial plus pre-filled diluent syringe (Prostap SR) 3.75mg pre-filled syringe (Prostap SR DCS) 11.25mg vial plus pre-filled diluent syringe (Prostap 3) 11.25mg pre-filled syringe (Prostap 3 DCS)	
	1. Endometriosis. 3.75mg every month for 6 months 2. Endometrial thinning. 3.75mg as a single dose 5 to 6 weeks prior to surgery 3. Uterine fibroids. 3.75mg every month for maximum of 6 months	
	Is titration required	No

6. Adverse drug reactions & special considerations <i>For a comprehensive list (including rare and very rare adverse effects), or if significance of possible adverse event uncertain, consult Summary of Product Characteristics or BNF</i>	Specialist to detail below the action to be taken upon occurrence of a particular adverse event as appropriate. Most serious toxicity is seen with long-term use and may therefore present first to GPs.		
	Adverse event System – symptom/sign	Action to be taken Include whether drug should be stopped prior to contacting secondary care specialist	By whom
	<i>Gastrointestinal effects (nausea, abdominal pain)</i>	<i>Contact Gynaecologist for advice if required</i>	<i>GP</i>
	<i>Headache or lightheadedness</i>	<i>Contact Gynaecologist for advice if required</i>	<i>GP</i>
	<i>Menopausal symptoms (if premenopausal)</i>	<i>Contact Gynaecologist for advice if required</i>	<i>GP</i>
	<i>Increase in menstrual bleeding</i>	<i>Contact Gynaecologist for advice if required</i>	<i>GP</i>
	The patient should be advised to report any of the above signs or symptoms to their GP without delay. Special considerations For the indications covered by this SCG treatment for longer than 6 months is not recommended because of increased risk of osteoporosis. Contraceptive precautions should be taken by all women of child-bearing potential throughout therapy. In women receiving GnRH analogues for the treatment of endometriosis the addition of hormone replacement therapy (HRT) has been shown to reduce bone mineral density loss and vasomotor symptoms. Therefore if appropriate HRT may be administered with GnRH analogue therapy after the assessment of the risks & benefits of treatment. Any adverse reaction to a black triangle drug or serious reaction to an established drug should be reported to the MHRA via the “Yellow Card” scheme.		
7. Ongoing monitoring requirements to be undertaken by GP	Is monitoring required?	Yes or No (if yes complete following section) NO	
8. Pharmaceutical aspects	No special considerations		
9. Secondary care contact information	Consultant gynaecologist to fill in their details below:		
	Name:		
	Contact number:		
	Hospital:		

10. Criteria for shared care	Prescribing responsibility will only be transferred when <ul style="list-style-type: none">▪ Treatment is for a specified indication and duration.▪ Treatment has been initiated and established by the secondary care specialist.▪ The patient's initial reaction to and progress on the drug is satisfactory.▪ The GP has agreed in writing/verbally(delete where appropriate) in each individual case that shared care is appropriate.▪ The patient's general physical, mental and social circumstances are such that he/she would benefit from shared care arrangements
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11. Responsibilities of initiating specialist

Assess patient & establish the need for therapy

Initiate treatment and review patient after 4 weeks and administer second dose

Clinical and biochemical supervision of patient

Dose adjustments

Evaluation of adverse events reported by GP or patient

Send letter to GP inviting shared care for the patient

Provision of therapy until shared care is agreed with GP

Six month review of patient

Advise GP if patient can safely receive HRT

Inform patient of effects and adverse effects of therapy

12. Responsibilities of the GP

The GP will notify the consultant if willing to accept shared care

Assessment of continued well being of patient

Adverse drug reaction monitoring

Issue of maintenance prescriptions

Ensure that practice nurses administering injections have received training relevant to the product

If the patient fails to attend or surgery is cancelled / postponed, the consultant is informed and the patient referred back to them

13. Responsibilities of the patient

To attend for their clinic appointments

To report adverse effects to their Specialist or GP

Shared Care Agreement Form

Specialist request

***IMPORTANT: ACTION NEEDED**

Dear Dr *[insert Doctors name here]*

Patient name: *[insert Patients name here]*

Date of birth: *[insert date of birth]*

Diagnosis: *[insert diagnosis here]*

This patient is suitable for treatment with *[insert drug name]* for the treatment of *[insert indication]*

This drug has been accepted for Shared Care according to the enclosed protocol (as agreed by Trust / LHB / AWMSG). I am therefore requesting your agreement to share the care of this patient.

Treatment was started on *[insert date started]* *[insert dose]*.

If you are in agreement, please continue monitoring and treatment from *[insert date]*
NB: date must be at least 1 month from initiation of treatment.

Baseline tests: *[insert information]*

Next review with this department: *[insert date]*

You will be sent a written summary within 14 days. The medical staff of the department are available at all times to give you advice. The patient will not be discharged from out-patient follow-up while taking *[insert text here]*.

Please use the reply slip overleaf and return it as soon as possible.

Thank you.

Yours

[insert Specialist name]

Shared Care Agreement Form

GP Response

Dear Dr *[insert Doctors name]*

Patient *[insert Patients name]*

Identifier *[insert patient date of birth/address]*

I have received your request for shared care of this patient who has been advised to start *[insert text here]*

- A I am willing to undertake shared care for this patient as set out in the protocol
- B I wish to discuss this request with you
- C I am unable to undertake shared care of this patient.

GP signature

Date

GP address/practice stamp