

Letrozole (off label use for infertility only)

Shared Care Guideline

Specialist Details	Patient Identifier
Name: _____	Date: _____
Location: _____	
Tel: _____	

Introduction

This shared care guideline refers to the off-label use of letrozole in the treatment of infertility.

Unlicensed indications:

Letrozole is indicated for the treatment of ovulatory failure in women with Polycystic ovarian syndrome like conditions desiring pregnancy. It is indicated only for patients in whom ovulatory dysfunction is demonstrated. Other causes of infertility must be excluded or adequately treated.

Adult dosage and administration

Treatment should be initiated with 2.5mg daily, on days 1-5 of cycle for up to 6 cycles.

In patients with amenorrhoea, treatment should be started within the first 5 days of a progestogen - induced withdrawal bleed.

If ovulation is induced, treatment may be continued for up to 6 cycles.

Preparations available:

- Letrozole 2.5 mg tablets

Hospital specialist responsibilities

- Assess patient is suitable for treatment. Baseline tests as per [NICE Fertility problems: assessment and treatment](https://www.nice.org.uk/guidance/TA255) *(www.nice.org.uk)
- Arrange shared care with the patient's GP.
- Advise GP on dose to be prescribed.
- Inform the patient that the use of letrozole is off-label and discuss the evidence for its use.
- Provide the patient/carer with relevant (written) information on use, including possible concerns and side-effects side effects in particular the risk of a multiple pregnancy and need for monitoring.
- Manufacturer advises caution in severe impairment and if creatinine clearance less than 10 mL/minute.
- Fertility monitoring: response to treatment.
- Offer ultrasound monitoring during at least the first cycle of treatment to ensure that they are taking a dose that minimises the risk of multiple pregnancy.
- Continue to review the patient at agreed specified intervals, sending a written summary to the GP whenever the patient is reviewed.
- Provide any other advice or information for the GP if required.

GP responsibilities

- Ensure that he/she has the information and knowledge to understand the therapeutic issues relating to the patient's clinical condition.
- Prescribe letrozole, continued prescribing is appropriate for patients attending regular review.
- Report any adverse drug reactions to initiating specialist and the usual bodies (e.g.CHM, MHRA).
- Adjust the dose as advised by the specialist.
- Regular monitoring will be undertaken by secondary care.

Adverse effects, precautions and contraindications

Adverse effects appear to be dose related, and are infrequent at the recommended dose. Multiple pregnancies, including simultaneous intrauterine and extrauterine pregnancies, have been reported. The more commonly reported side-effects are:

- hot flushes.
- hypercholesterolemia.
- arthralgia.
- fatigue.
- headache.
- increased sweating.
- nausea.
- vaginal haemorrhage.

A rare, but more serious side-effect is ovarian hyperstimulation: refer back to initiating specialist

Precautions: a history of:

- Ovarian hyperstimulation syndrome.
- multiple pregnancy.
- ectopic pregnancy.
- uterine fibroids.
- ovarian cancer.

Contraindications:

- pregnancy.

Common drug interactions

Letrozole inhibits cytochrome P450 isoenzymes. The clinical relevance of this is unknown. Caution is therefore indicated when giving letrozole concomitantly with medicinal products whose elimination is mainly dependent on these isoenzymes and whose therapeutic index is narrow (e.g. phenytoin, clopidogrel).

Communication

For any queries relating to this patient's treatment with letrozole, please contact the specialist named at the top of this document.

This information is not inclusive of all prescribing information and potential adverse effects.
Please refer to full prescribing data in the SPC or the BNF

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