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Dear Doctor

Shared Care Prescribing of AMBER drugs - Goserelin (Zoladex)

The Avon Prescribing and Therapeutics committee has set up a system of drug classification – the traffic light system to clarify the prescribing of drugs by hospital specialists and General Practitioners.

Drugs which are classified as amber should be prescribed by a "secondary care specialist or competent clinician". The patient needs to be stabilised and reviewed before asking the GP to take over clinical and prescribing responsibility. The traffic light booklet states that transfer from secondary to primary care can be considered if:

1, The patient is stabilised on the drug which is being used for the indication listed.
2, The GP has agreed to accept clinical and prescribing responsibility for an individual patient.
3, Shared care guidance has been developed and sent to the GP before the transfer of clinical and prescribing responsibility.

It is also noted in the booklet that a prescriber is free to *not* accept clinical responsibility because of lack of familiarity or competence in the use of the drug, or if it is used outside agreed guidance. Prescribers however may not refuse clinical responsibility on the grounds of cost.

We have therefore adopted the following protocol and would ask if you could now take over the prescribing and clinical responsibility for your patient. We gave the first injection of goserelin four weeks ago and have just reviewed her in the clinic. There were no significant side effects and we are happy that she is stabilised on the drug. She has been given another injection and will contact you before she needs the next one. We would be grateful if you would be able to continue this, saving her further visits to hospital.

If you have any further questions or are not happy with this please let us know.

Details

1. Goserelin (Zoladex) is being used for the management of breast cancer.
2, Background – Goserelin is a Luteinising Hormone Releasing Hormone agonist (LHRHa). It works by binding to LHRH receptors in pituitary cells, reducing the number of available receptors, which reduces the secretion of LH and thereby reduces the level of circulating oestradiol in pre-menopausal women to the level of post-menopausal women within 21 days, after an initial surge. Its use in breast cancer is in hormone sensitive tumours in pre-menopausal women, which can either be in the adjuvant setting or in the treatment of advanced breast cancer. In adjuvant treatment, after primary surgery and/or radiotherapy and/or chemotherapy, there is evidence that disease free survival is increased by adding goserelin to tamoxifen. The trials are still running and therefore treatment tends to be offered to those women with worse prognostic factors at present.

3, The aims of treatment in your patient are thus either to treat her advanced breast cancer or to give adjuvant treatment.

4, The dose is invariably 3.6mg given as a subcutaneous injection into the anterior abdominal wall, either using local anaesthetic infiltration, ethyl chloride spray, EMLA cream or no anaesthetic at all. This is given every 28 days. Some people use the 10.8 mg injection every 12 weeks, but this is not licensed for use in women. Treatment will continue for 2 to 5 years after surgery in the case of adjuvant treatment or until the woman becomes post-menopausal naturally, but the only way of finding this out is to stop the treatment and wait to see if the periods return or after waiting measure her FSH/LH levels. In the case of advanced disease, until we feel that there is lack of clinical response. Obviously we will take clinical responsibility for the monitoring of advanced disease.

5, There are no routine monitoring tests required.

6, The main side effects are those of oestrogen deprivation similar to an early menopause – Hot flushes, vaginal dryness, sexual dysfunction and urinary infections. Less common side effects may include rash, nausea, injection site reactions, rarely hypersensitivity reactions, headache (rarely migraine) arthralgia, hair loss, peripheral oedema, gastro-intestinal disturbances, weight loss, sleep disorders and mood changes

7, Interactions – Caution is required in women with metabolic bone disease because decreases in bone mineral density may occur.

8, Cautions – concurrent HRT should not be given, but topical oestrogen cream or vaginal tablets may be used.

9, Points for the patient – This treatment will probably benefit you in terms of survival, over and above tamoxifen, but does involve monthly injections and worse menopausal symptoms

10, Contact Details– If there are any problems, either generally or about specific patients, please contact us as per the letter heading either by letter, e-mail or by telephone when you will be able to speak to a breast specialist during working hours.

11, This document has been prepared by Dr. M. H. Shere, Staff Grade Breast Clinician in March 2003 and reviewed by consultant colleagues. It will be reviewed annually.

Yours Sincerely

Mr S.J Cawthorn, Consultant Breast Surgeon
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