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Questions and answers on Femara and associated names (letrozole, 2.5 mg tablets)

Outcome of a procedure under Article 30 of Directive 2001/83/EC

On 15 March 2012, the European Medicines Agency completed a review of Femara. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that there is a need to harmonise the prescribing information for Femara in the European Union (EU).

What is Femara?

Femara is a medicine that contains the active substance letrozole. It is used as hormonal treatment in postmenopausal women with breast cancer.

The active substance in Femara, letrozole, is an 'aromatase inhibitor'. This means that it works by blocking the action of an enzyme called 'aromatase', which is involved in the production of the hormone oestrogen. In some types of breast cancer (hormone receptor positive or hormone-dependent types), oestrogen is known to stimulate the growth of the cancer cells. By blocking the activity of aromatase and thereby reducing the amount of oestrogen produced, the medicine slows or stops the growth and spread of the cancer.

Femara is used in postmenopausal women because aromatase is involved in producing most of the oestrogen in this population.

Femara is marketed in all EU Member States and is also available under other trade names: Femar, Fémara, and Loxifan.

The company that markets these medicines is Novartis.

Why was Femara reviewed?

Femara is authorised in the EU via national procedures. This has led to divergences across Member States in the way the medicine can be used, as seen in the differences in the summaries of product characteristics (SmPCs), labelling and package leaflets in the countries where the medicine is marketed.

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Femara was identified as needing harmonisation by the Co-ordination Group on the Mutual and Decentralised Procedures – Human (CMD(h)).

On 31 August, the European Commission referred the matter to the CHMP in order to harmonise the marketing authorisations for Femara in the EU.

What are the conclusions of the CHMP?

The CHMP, in light of the data submitted and the scientific discussion within the Committee, was of the opinion that the SmPCs, labelling and package leaflets should be harmonised across the EU.

The main areas harmonised include:

4.1 Therapeutic indications

After reviewing the available data supporting the medicine's use, the CHMP agreed that Femara should be used in postmenopausal women for the following:

- Adjuvant (post-surgery) treatment of hormone receptor positive invasive early breast cancer.
- Extended adjuvant treatment of hormone-dependent invasive breast cancer in women who have received prior standard adjuvant tamoxifen therapy for five years.
- First-line treatment for hormone-dependent advanced breast cancer.
- Advanced breast cancer after relapse or disease progression, in women with natural or artificially induced postmenopausal endocrine status, who have previously been treated with anti-oestrogens.
- Neo-adjuvant (pre-surgery) treatment of hormone receptor positive, HER-2 negative breast cancer where chemotherapy is not suitable and immediate surgery not indicated.

4.2 Posology and method of administration

Having harmonised the indications, the CHMP also harmonised recommendations on the doses, duration of treatment and use of Femara in patients with reduced kidney or liver function.

4.3 Contra-indications

In harmonising the contraindications, the CHMP decided against including two contraindications that were in the SmPCs of some EU countries: liver impairment and pre-operative use in patients whose receptor status is negative or unknown. The CHMP was of the view that it was more appropriate to include relevant warnings in section 4.4.

Other changes

The CHMP also harmonised other sections of the SmPC including sections 4.6 (pregnancy and lactation) and 4.8 (side effects).

The amended information to doctors and patients is available here.

The European Commission issued a decision on 22 May 2012.