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Questions and answers on Arimidex (anastrozole, 1 mg tablets)

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

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

What is Arimidex?

Arimidex is a medicine that contains the active substance anastrozole. It is used to treat breast cancer in women who have already gone through the menopause. Arimidex belongs to a group of medicines called 'aromatase inhibitors' which reduce the amount of the hormone oestrogen made in the body by blocking the action of an enzyme in the body called 'aromatase'. Decreasing the production of oestrogen is a way of suppressing the growth of the breast cancer because the growth of breast tissue is stimulated by oestrogen.

The company that markets Arimidex is AstraZeneca. The medicine is available in all Member States of the European Union as well as Iceland and Norway.

Why was Arimidex reviewed?

Arimidex is authorised in the EU via mutual recognition and 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.

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

On 22 July 2010, the European Commission referred the matter to the CHMP in order to harmonise the marketing authorisations for Arimidex in the EU.

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What are the conclusions of the CHMP?

The CHMP, in the 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 areas harmonised include:

4.1 Therapeutic indications

The CHMP agreed that Arimidex should be used for:

- Treatment of hormone receptor-positive advanced breast cancer in postmenopausal women. 'Hormone receptor-positive' means that the cancer depends on the presence of oestrogen in order to grow.
- Adjuvant (add-on) treatment of hormone receptor-positive early invasive breast cancer in postmenopausal women, including those who have received two to three years of adjuvant tamoxifen (another anti-cancer medicine).

4.2 Posology and method of administration

The recommended dose for adults, including elderly patients, is one 1 mg tablet once a day. The same dose is recommended in patients with mild liver problems or with mild to moderate kidney problems.

For postmenopausal women with hormone receptor-positive early invasive breast cancer, the recommended duration of adjuvant endocrine treatment is five years.

4.3 Contra-indications

Arimidex must not be used in:

- Pregnant or breast-feeding women.
- Patients known to be hypersensitive (allergic) to the active substance anastrozole, or to any of the other ingredients.

Other changes

The Committee also harmonised other sections of the SmPC, including the Special Warnings, which state that tamoxifen and oestrogen-containing therapies should not be given with Arimidex and that Arimidex should be used with caution in patients with severe kidney problems or moderate to severe liver problems.

The amended information to doctors and patients is available here.

The European Commission issued a decision on 19 May 2011.