European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

FARESTON

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Fareston?
Fareston is a medicine that contains the active substance toremifene. It is available as white, round tablets (60 mg).

What is Fareston used for?
Fareston is used to treat hormone-dependent metastatic breast cancer in women who have been through the menopause. 'Metastatic' means that the cancer has spread to other parts of the body. Fareston is not recommended for patients with oestrogen-receptor-negative tumours (where the cancer cells do not have receptors for the hormone oestrogen on their surface).
The medicine can only be obtained with a prescription.

How is Fareston used?
The recommended dose of Fareston is one tablet once a day. It should be used with caution in patients who have problems with their liver.

How does Fareston work?
Most types of breast cancer grow in response to the hormone oestrogen. The active substance in Fareston, toremifene, is an anti-oestrogen. It attaches to the receptors for oestrogen on the surface of cells, where its main effect is to block the effects of the hormone. As a result, the tumour cells are not stimulated to grow by oestrogen and the growth of the tumour is reduced.

How has Fareston been studied?
The effects of Fareston were first tested in experimental models before being studied in humans. Fareston has been studied in 1,869 postmenopausal women with metastatic breast cancer in four main studies. The effects of Fareston were compared with those of tamoxifen (another anti-oestrogen used to treat breast cancer). The main measures of effectiveness were response rate (the number of patients whose tumours responded to treatment), time to progression (the length of time until the disease got worse) and survival.

What benefit has Fareston shown during the studies?
The effectiveness of Fareston and tamoxifen were equivalent. Looking at the results of the three largest main studies taken together, patients taking Fareston had similar response rates, times to

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progression and survival rates as the patients taking tamoxifen. This was confirmed in the fourth study.

What is the risk associated with Fareston?
The most common side effects with Fareston (seen in more than 1 patient in 10) are hot flushes and sweating. For the full list of all side effects reported with Fareston, see the Package Leaflet.
Fareston should not be used in people who may be hypersensitive (allergic) to toremifene or any of the other ingredients. It must not be used on a long-term basis in patients who have endometrial hyperplasia (thickening of the lining of the womb) or severe liver problems. Fareston must not be used in patients with 'QT prolongation' (a disruption of the electrical activity of the heart), electrolyte disturbances (altered levels of salts in the blood) especially hypokalaemia (low potassium levels), bradycardia (a very slow heart rate), heart failure (an inability of the heart to pump enough blood to the rest of the body) or a history of symptomatic arrhythmias (abnormal heart rhythms), or in patients also taking other medicines that can cause QT prolongation. A list of these medicines is given in the Package Leaflet.

Why has Fareston been approved?
The Committee for Medicinal Products for Human Use (CHMP) concluded that the benefits and risks of Fareston were comparable to those of tamoxifen in women with oestrogen-receptor-positive tumours. Therefore, the Committee decided that Fareston's benefits are greater than its risks for the first line hormone treatment of hormone-dependent metastatic breast cancer in postmenopausal patients. The Committee recommended that Fareston be given marketing authorisation.

Other information about Fareston:
The European Commission granted a marketing authorisation valid throughout the European Union for Fareston on 14 February 1996. The marketing authorisation was renewed on 14 February 2001 and on 14 February 2006. The marketing authorisation holder is Orion Corporation.

The full EPAR for Fareston can be found here.

This summary was last updated in 03-2009.