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Questions and answers on the addition of contraindications for Fareston (toremifene)

As part of its continuous monitoring of medicines, the European Medicines Agency (EMA) has reviewed the available information on the safety of Fareston (toremifene), in particular the medicine's effects on the heart. The EMA's Committee for Medicinal Products for Human Use (CHMP) has concluded that Fareston's benefits continue to outweigh its risks. However, it recommended that patients at risk of disruptions to the electrical activity of the heart should not be prescribed Fareston.

What is Fareston?

Fareston is a medicine that 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, and 'hormone dependent' means that it grows in response to the hormone oestrogen. The active substance in Fareston, toremifene, works by blocking the effects of oestrogen, reducing the growth of the cancer.

Fareston has been authorised in the European Union since February 1996, and is marketed in 18 Member States.

What is the issue with the safety of Fareston?

The CHMP reviewed the safety information for Fareston because of concerns over its effects on the heart. In particular, the Committee was concerned that Fareston could cause the 'QT interval' (part of the heartbeat) to last for longer than normal. This side effect, called 'QT prolongation', is known to be linked to fainting and disruption of the heart rhythm.

The Committee reviewed a study of 250 men who were given Fareston at one of three doses, moxifloxacin (a medicine that is known to cause QT prolongation) or placebo (a dummy treatment). The patients who took Fareston were shown to have prolongations in the QT interval, which were similar to those in patients taking moxifloxacin. The effect of Fareston on the heart was greater with higher doses of Fareston.

Although the study was carried out in men, the results were also considered to be important for women, particularly because women tend to have longer QT intervals than men and may be more susceptible to this side effect when they take Fareston.

The Committee completed its review at its meeting of 19-22 January 2009.

What are the conclusions of the CHMP?

The CHMP concluded that Fareston's benefits continue to outweigh its risks for the treatment of hormone-dependent metastatic breast cancer in postmenopausal women. However, it recommended a change to the Product Information to include a contraindication to the use of Fareston in patients at risk of having prolonged QT intervals.

The Committee recommended that Fareston must not be used in patients who already have prolonged QT intervals or in combination with other medicines that can cause QT prolongation. It also recommended that it must not be used in patients who are at risk of disruptions of the heart rhythm, including patients with the following conditions:

- altered levels of salts in the blood, especially low potassium levels;
- a very slow heart rate;

- an inability of the heart to pump enough blood to the rest of the body;
- a history of abnormal heart rhythm.

What is the advice to patients and prescribers?

- Doctors should prescribe Fareston according to the updated Product Information.
- Patients who are taking Fareston and have any questions or concerns should talk to their doctor or pharmacist.

The CHMP opinion will now be sent to the European Commission for the adoption of a formal decision, applicable in all EU countries.

For further information, see the [updated Product Information](#) adopted by the CHMP on 22 January 2009. The full EPAR for Fareston can be found [here](#).