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EMA reviewing cancer medicine docetaxel

Preliminary assessment show no increase in frequency of known side effect

The European Medicines Agency (EMA) is investigating the cancer medicine docetaxel following cases of neutropenic enterocolitis in patients in France, most of whom were being treated for operable breast cancer. Neutropenic enterocolitis is a serious inflammatory condition of the intestine associated with neutropenia (low levels of neutrophils, a type of white blood cell that fights infection). It is a known and rare side effect of docetaxel (which may affect up to one in 1,000 people).

A preliminary assessment by EMA's Pharmacovigilance Risk Assessment Committee (PRAC) indicates that the frequency of this side effect has not increased in the last two years. A thorough evaluation of available data is being carried out and final conclusions will be published once the review is completed.

Docetaxel is an important therapeutic option which has been shown to extend the lives of cancer patients. While the review is ongoing, EMA advises that doctors should continue to prescribe this medicine according to recommendations in the current product information, including detailed recommendations for the prevention and management of neutropenia.

Patients who have any questions about their treatment should speak to their doctor.

More about the medicine

Docetaxel is a medicine used for the treatment of several types of cancer, including breast cancer. It has been authorised in the EU since 1995 under several trade names including Taxotere. More information on docetaxel medicines is available here.

More about the procedure

The review of docetaxel is being carried out in the context of a safety signal. A safety signal is information on a new or incompletely documented adverse event that is potentially caused by a medicine and that warrants further investigation.

* The document has been updated to amend the frequency of neutropenic enterocolitis from 'up to one in 10,000' to 'up to one in 1,000'

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The review is being carried out by EMA's Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines. Once the review is completed, the PRAC will make any recommendations necessary to minimise risks and protect patients' health.

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