



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## PRAC concludes there is no evidence of a change in known risk of neutropenic enterocolitis with docetaxel

Doctors advised to follow recommendations in current product information

EMA's Pharmacovigilance Risk Assessment Committee (PRAC) has concluded that there is no evidence of a change in the known risk of neutropenic enterocolitis after treatment with docetaxel, a cancer medicine.

Neutropenic enterocolitis is a serious inflammatory condition of the intestine which may occur in up to 1 in 1,000 cancer patients taking the medicine.

Having considered available data on docetaxel, the Committee concluded that the recent rise in reporting of the condition observed in France could be due to an increased awareness among healthcare professionals. Reporting rates in the EU as a whole do not provide any evidence of an increase in the incidence of neutropenic enterocolitis.

Neutropenic enterocolitis remains a rare side effect of docetaxel and will continue to be under routine monitoring and evaluated during periodic reviews of docetaxel medicines.

Doctors prescribing docetaxel are advised to follow recommendations in the current product information, including those concerning the prevention and management of neutropenia (low white blood cell counts) which occurs in patients with the condition. Patients who have any questions about their treatment should speak to their doctor.

Docetaxel is an important therapeutic option in cancer treatment and has been shown to extend the lives of patients, including those with breast, prostate and lung cancers.

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### More about the medicine

Docetaxel is a medicine used for treating several types of cancers: breast cancer, non-small-cell lung cancer, prostate cancer, gastric adenocarcinoma (a type of stomach cancer) and head and neck cancer. It has been authorised in the EU since 1995 under several trade names including Taxotere. More information on docetaxel medicines is available on [EMA's website](#).



### **More about the procedure**

The review of docetaxel was 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 review was carried out by EMA's Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines.