EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update of 19 September 2016:

The shortage affecting Taxotere has been resolved and the below information and recommendations which were issued during the shortage no longer apply.

9 June 2016
EMA/403928/2016 Rev. 1

Shortage of Taxotere (docetaxel)
concentrate for solution for infusion vial (20mg / 1 ml and 80mg / 4ml)

Indication

Taxotere is used to treat the following cancers: breast cancer, non-small-cell lung, prostate cancer, gastric adenocarcinoma (a type of stomach cancer), and head and neck cancer.

Reason for shortage

A failure in the filling process at a manufacturing site in Germany has led to Taxotere vials being up to 5 % over-concentrated. The vials contain the same total amount of active substance but in a smaller volume. Sanofi on behalf of the marketing authorisation holder for Taxotere, has therefore initiated a recall (see list of batches below) of affected batches.

Some of the vials released to the market may have already been used. There is a small risk that patients who have received the affected vials may have received more docetaxel than was intended.

As a consequence of the recall Taxotere 20mg/1 ml and 80 mg/4ml concentrate for solution for infusion may become unavailable in some EU member states. Normal supply is expected to resume on 19 August 2016.

Table 1. Recalled batches

Vial size	Taxotere (batch numbers)
1 ml	4F180, 5F189, 5F200, 5F201, 5F206, 5F207, 5F218, 5F223,6F239
4 ml	5F199, 5F209, 5F219, 5F225, 6F237, 6F240

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Shortage of Taxotere (docetaxel)
concentrate for solution for infusion vial (20mg / 1 ml and 80mg / 4ml)

Member States affected[1]	Temporary supply disruption may occur in the following EU Member States: France, Ireland, Italy and Spain.
Information to healthcare professionals	• Batches of Taxotere 20 mg/1ml and 80 mg/4ml concentrate for solution for infusion vial have been recalled in some EU member states due to a failure in the manufacturing process which has resulted in vials being up to 5% over-concentrated. This means that the vials contain the total amount of docetaxel in a smaller volume. There is a small risk that patients who have received the affected vials received an overdose which could lead to an increase in severity and frequency of known adverse events. • Healthcare providers should carefully monitor all patients who have received the affected vials for signs of toxicity and treat these as appropriate. Any suspected adverse reactions should be reported to the national competent authority. • As a consequence of the recall, Taxotere 20 mg/1ml and 80 mg/4ml concentrate for solution for infusion may become unavailable in some EU member states and patients may have to be switched to an alternative docetaxel-containing medicine. • Additional advice may be available from the national competent authority.
Information to patients	• Some batches of Taxotere have been recalled in EU member states due to a problem in the manufacturing process which could have led to vials being too concentrated. • There is a small risk that patients who have received the affected vials received too much of the medicine which could increase their risk of side effects. • In case you have received any of the affected vials your doctor will monitor you closely for any side effects and treat you as needed. As a consequence of the recall, Taxotere 20mg/1 ml and 80 mg/4ml concentrate for solution for infusion may become unavailable. As other docetaxel-containing medicines are available your doctor will switch you to an alternative docetaxel-containing medicine if needed.

[1] This information may change. For accurate information about the status of a medicine shortage in a particular Member State the national competent authority should be contacted.

	• Patients who get any side effects should talk to their doctor or pharmacist. • Patients who have any questions should speak to their national competent authority. • Additional advice may be available from the national competent authority.