



**One-vial Taxotere® (docetaxel) Injection Concentrate: Risk of stopper coring
with use of large gauge needles
Concerning All One-vial Taxotere Presentations**

Dear Healthcare Professional

14th-November-2011

Sanofi wishes to inform you of important information regarding the preparation of one-vial Taxotere.

A 21 gauge needle should be used when preparing 1-vial Taxotere distributed by Sanofi. This needle size recommendation is based on our receipt of reports of particles in the transfer syringe when preparing 1-vial Taxotere with a 19 gauge needle. The particles were discovered during visual inspection of the transfer syringe prior to injecting the drug into the final infusion solution. Sanofi obtained samples of the particles observed in the transfer syringe and the particle fragments have been identified as rubber from the 1-vial Taxotere vial stopper.

We have received no reports of patients receiving final infusion solution containing stopper particles. Further examination of the 1-vial stoppers by sanofi-aventis confirmed their compliance with applicable specification requirements.

Please be aware that stopper coring may occur when 18 or 19 gauge needles are used in the preparation of one-vial Taxotere. For this reason a **21-gauge needle** should be used when withdrawing the required amount of docetaxel from 1-vial Taxotere. One-vial Taxotere should always be inspected visually for particulate matter or discoloration prior to administration whenever the solution and container permit. Sanofi has not received any reports of stopper coring using a 21-gauge needle during the preparation of Taxotere.

The product information has been revised to include this information.

Call for reporting:

Healthcare professionals should report any serious adverse events suspected to be associated with the use of Taxotere to The Irish Medicines Board **using the on-line reporting function on the IMB website (www.imb.ie) or alternatively by contacting the IMB at 01 6764971.**

In addition, this information may be reported to Sanofi Ireland Ltd., please phone 01-4035600.

Communication information

If you have any questions or require additional information, please contact our Medical Information Department 01-4035600 or email IEmedinfo@sanofi.com

Yours sincerely,

A handwritten signature in black ink, appearing to read "Dr. Valcheva", is written over a horizontal line.

Dr. Velichka Valcheva
Medical Director
Sanofi-aventis Ireland