



sanofi aventis

Because health matters

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Ms
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Dear Ms

Thank you for your enquiry requesting the following information on Taxotere - docetaxel:

Taxotere and incidence of permanent alopecia

As you are aware from the Taxotere Summary of Product Characteristics alopecia is a very common ($\geq 10\%$ incidence) side effect seen with all licensed combinations of docetaxel. As you can appreciate, it is very difficult to determine the incidence of permanent alopecia as most of the information regarding alopecia will have come from clinical trials which are of limited period. Therefore for your interest, please find below information on prolonged alopecia, with one reference of non-reversible alopecia being identified.

In particular, clinical studies involving $100\text{mg}/\text{m}^2$ monotherapy¹ showed one case of non-reversible alopecia at the end of the study and studies involving Taxotere in combination with doxorubicin and cyclophosphamide² observed alopecia to be ongoing at the median follow-up time of 55 months in 3% of patients at the end of the chemotherapy.

There are no specific fully published studies assessing the incidence of prolonged alopecia in patients receiving docetaxel chemotherapy. One retrospective review presented at the San Antonio Breast Cancer Symposium in 2006³ assessed prolonged significant alopecia in breast cancer patients. Patients received various chemotherapy and were stratified based on regimen; Group A - doxorubicin without taxane, Group B - doxorubicin with paclitaxel, and Group C - doxorubicin with docetaxel. Of the 496 patient assessed, 7 had prolonged significant alopecia at a median of five years follow up. All of these patients were in Group C having received docetaxel as AC-T, although two had discontinued docetaxel after one dose due to toxicities.