

AventisPharmaceuticals



March 27, 2001

URGENT: VOLUNTARY DRUG RECALL

TAXOTERE® (docetaxel) for Injection Concentrate 20-mg NDC# 0075-8001-20

Dear Health Care Professional :

Aventis Pharmaceuticals is initiating a voluntary recall of Taxotere® (docetaxel) for Injection Concentrate 20-mg active and diluent vials. The lot numbers for this recall are: **0P273 (active) which was packaged together with diluent vials with the following lot numbers 0T446 (diluent) or 0T449 (diluent).**

It has been determined that the Taxotere 20mg vial containing the active ingredient may have inadvertently been labeled as a "diluent" vial. Aventis has received one product complaint related to this mislabeling. We believe this to be an isolated event, but are nevertheless recalling the affected lots.

Please proceed with the following:

1. Examine your inventory immediately to determine if you have cartons of Taxotere 20-mg vials with the lot numbers listed above.
2. Place any affected inventory on hold. You will receive a business reply card, packing slip and return label in the mail from National Notification Center within 3 – 5 days.
3. On receipt of the returned product, you will be issued a credit from your distributor.
4. Taxotere can immediately be reordered through normal distribution channels.

We ask that you please communicate this information to anyone who may have purchased the affected lots of Taxotere from your facility. If you have any questions regarding this recall, you may contact our Customer Service Department at 1-800-207-8049. For Medical Information questions or to report an Adverse Event please call, 1-800-633-1610. We appreciate your assistance; we apologize for the inconvenience and assure you that Taxotere 20-mg is available immediately for order.

Sincerely,

A handwritten signature in black ink, appearing to read "John Leone".

John Leone
Sr. Vice President & Chief Operating Officer
US Commercial Operations