



FDA Drug Safety Communication: FDA warns that cancer drug docetaxel may cause symptoms of alcohol intoxication after treatment

Safety Announcement

[6-20-2014] The U.S. Food and Drug Administration (FDA) is warning that the intravenous chemotherapy drug docetaxel contains ethanol, also known as alcohol, which may cause patients to experience intoxication or feel drunk during and after treatment. We are revising the labels of all docetaxel drug products to warn about this risk. Health care professionals should consider the alcohol content of docetaxel when prescribing or administering the drug to patients, particularly in those whom alcohol intake should be avoided or minimized and when using it in conjunction with other medications.

Patients should be aware that docetaxel may cause them to become intoxicated from the alcohol it contains. Patients should avoid driving, operating machinery, or performing other activities that are dangerous for one to two hours after the infusion of docetaxel. In addition, some medications, such as pain relievers and sleep aids, may interact with the alcohol in the docetaxel infusion and worsen the intoxicating effects.

Docetaxel is a prescription chemotherapy drug used to treat different kinds of cancer, including cancers of the breast, prostate, stomach, head and neck cancers, and non-small-cell lung cancer. Several forms of docetaxel are currently marketed, including generics and the brand-name products Taxotere, Docefrez, and Docetaxel Injection. The various products contain different amounts of alcohol, which is used to dissolve the active ingredients so docetaxel can be given intravenously (see Docetaxel Formulations and Alcohol Content). Health care professionals should be aware of the differences in formulations in order to monitor and counsel patients appropriately.

Facts about docetaxel

- A prescription chemotherapy drug used to treat different types of cancer, including breast, prostate, stomach, head and neck cancers, and non-small cell lung cancer
- Marketed as generics and also under the brand-names Taxotere, Docefrez, and Docetaxel Injection
- Given as an infusion into the vein in a physician's office or a medical facility capable of managing possible complications

Additional Information for Patients

- Docetaxel contains alcohol, which affects the central nervous system and can impair your ability to drive or use machinery for one to two hours after infusion.
- Before receiving docetaxel, tell your health care professional if you have problems with alcohol or drinking, have liver disease or other medical conditions that may be affected by alcohol intake.
- Avoid driving, operating machinery or doing other activities that are dangerous or require skill one to two hours after you receive treatment with docetaxel.
- Tell your health care professional about all the medicines you are currently taking, as the alcohol in docetaxel may affect other medicines you are using.
- Notify your health care professional immediately if you experience any of the following symptoms while receiving an intravenous infusion of docetaxel and for one to two hours after treatment: symptoms of being drunk, confusion, stumbling, or becoming very sleepy.
- Report any side effects from docetaxel to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of this page.

Additional Information for Health Care Professionals

- Cases of intoxication have been reported with some formulations of docetaxel due to the alcohol (ethanol) content.
- The alcohol content in a dose of docetaxel may affect the central nervous system and should be taken into account for patients in whom alcohol intake should be avoided or minimized, including patients with hepatic impairment.
- Take into consideration the alcohol content in docetaxel on patients' ability to drive or use machines one to two hours after the infusion.
- Consider a docetaxel formulation with the lowest possible alcohol content for patients who experience adverse reactions.
- Slowing the infusion rate during administration may help resolve symptoms of alcohol intoxication.
- Monitor patients for signs of alcohol intoxication during and after treatment.
- Counsel patients about the possible effects of the alcohol content in docetaxel, including possible effects on the central nervous system.
- Report adverse events involving docetaxel to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of this page.

Data Summary

A search of the FDA Adverse Event Reporting System (FAERS) database and the medical literature identified three cases of alcohol intoxication associated with docetaxel.¹ There was a strong temporal association between the docetaxel infusion and symptoms of alcohol intoxication in the cases. Two patients experienced alcohol intoxication during the infusion and one patient experienced it within 24 hours of drug administration. In one case, the symptoms of alcohol intoxication were transient. In another case, the symptoms resolved in time for the patient to finish his treatment using a slower infusion rate. In two of the three cases, the reporters planned to use a different docetaxel formulation with lower alcohol content for future treatments.

Docetaxel Formulations and Alcohol (Ethanol) Content

| Product | Manufacturer | Alcohol (ethanol) content (grams) in 200 mg dose* |
|-------------------------------|--------------|---|
| Docetaxel Injection | Pfizer | 6.4 |
| Docetaxel Injection | Sandoz | 5.5 |
| Docetaxel Injection | Accord | 4.0 |
| Docetaxel Injection | Actavis | 4.0 |
| Taxotere one vial formulation | Sanofi | 4.0 |
| Docetaxel Injection | Hospira | 3.7 |
| Docefrez | Sun Pharma | 2.9 |
| Taxotere two vial formulation | Sanofi | 2.0 |

* Assumes maximum dose of 100 mg/m^2 , body surface area = 2.0 m^2

Reference

1. Mirza A, Mithal N. Alcohol intoxication with the new formulation of docetaxel. Clin Oncol (R Coll Radiol) 2011;23:560-1.