HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use TAXOTERE safely and effectively. See full prescribing information for TAXOTERE.

TAXOTERE (docetaxel) Injection Concentrate, Intravenous Infusion (IV). Initial U.S. Approval: 1996

WARNING
See full prescribing information for complete boxed warning
- Treatment-related mortality increases with abnormal liver function, at higher doses, and in patients with NSCLC and prior platinum-based therapy receiving TAXOTERE at 100 mg/m^2 (5.1)
- Should not be given if bilirubin > ULN, or if SGOT and/or SGPT > 1.5 x ULN concomitant with alkaline phosphatase > 2.5 x ULN. LFT elevations increase risk of severe or life-threatening complications. Obtain LFTs before each treatment cycle (8.6)
- Should not be given if neutrophil counts are < 1500 cells/mm^3. Obtain frequent blood counts to monitor for neutropenia (4)
- Severe hypersensitivity, including very rare fatal anaphylaxis, has been reported in patients who received dexamethasone premedication. Severe reactions require immediate discontinuation of TAXOTERE and administration of appropriate therapy (5.3)
- Contraindicated if history of severe hypersensitivity reactions to TAXOTERE or to drugs formulated with polysorbate 80 (4)
- Severe fluid retention may occur despite dexamethasone (5.10)

----------RECENT MAJOR CHANGES----------
Indications and usage (1), dosage and administration (2), warnings and precautions (5), adverse reactions(6), 09/28/07

----------INDICATIONS AND USAGE----------
Taxotere is a microtubule inhibitor used for:
Breast Cancer (BC): single agent for locally advanced or metastatic BC after chemotherapy failure; and with doxorubicin and cyclophosphamide as adjuvant treatment of operable node-positive BC (1.1)
Non-Small Cell Lung Cancer (NSCLC): single agent for locally advanced or metastatic NSCLC after platinum therapy failure; and with cisplatin for unresectable, locally advanced or metastatic untreated NSCLC (1.2)
Hormone Refractory Prostate Cancer (HRPC): with prednisone in androgen independent (hormone refractory) metastatic prostate cancer (1.3)
Gastric Adenocarcinoma (GC): with cisplatin and fluorouracil for untreated, advanced GC, including the gastroesophageal junction (1.4)
Squamous Cell Carcinoma of the Head and Neck Cancer (SCCHN): with cisplatin and fluorouracil for induction treatment of locally advanced SCCHN (1.5)

----------DOSAGE AND ADMINISTRATION----------
Administer under supervision of qualified physicians experienced in using antineoplastic agents. Facilities to manage possible complications must be available.
Administer IV over 1 hr every 3 weeks. PVC equipment is not recommended.
- BC: locally advanced or metastatic: 60-100 mg/m^2 single agent (2.1)
- BC adjuvant: 75 mg/m^2 administered 1 hour after doxorubicin 50 mg/m^2 and cyclophosphamide 500 mg/m^2 every 3 weeks for 6 cycles (2.1)
- NSCLC: after platinum therapy failure: 75 mg/m^2 single agent (2.2)
- NSCLC: chemotherapy-naive: 75 mg/m^2 followed by cisplatin 75 mg/m^2 (2.2)
- HRPC: 75 mg/m^2 with 5 mg prednisone twice a day continuously (2.3)
- GC: 75 mg/m^2 followed by cisplatin 75 mg/m^2 (both on day 1 only) followed by fluorouracil 750 mg/m^2 per day as a 24-hr IV (days 1-5), starting at end of cisplatin infusion (2.4)
- SCCHN: 75 mg/m^2 followed by cisplatin 75 mg/m^2 IV (day 1), followed by fluorouracil 750 mg/m^2 per day as a 24-hr IV (days 1-5), starting at end of cisplatin infusion; for 4 cycles (2.5)
- SCCHN: 75 mg/m^2 followed by cisplatin 100 mg/m^2 IV (day 1), followed by fluorouracil 1000 mg/m^2 per day as a 24-hr IV (days 1-4); for 3 cycles (2.5)

Premedication Regimen (2.6)
- Oral corticosteroids such as dexamethasone 16 mg per day (*e.g.*, 8 mg twice a day) for 3 days starting 1 day before administration
- HRPC: oral dexamethasone 8 mg, at 12, 3, and 1 hrs before treatment

Dosage adjustments during treatment see full prescribing information (2.7)

----------DOSAGE FORMS AND STRENGTHS----------
- Single dose vial 80 mg/2 mL and diluent, 20 mg/0.5 mL and diluent (3)

----------CONTRAINDICATIONS----------
- Hypersensitivity to Taxotere or polysorbate 80 (4)
- Neutrophil counts of < 1500 cells/mm^3 (4)

----------WARNINGS AND PRECAUTIONS----------
- Acute myeloid leukemia (5.6)
- Fetal harm can occur when administered to a pregnant woman. Women of childbearing potential should be advised not to become pregnant when taking TAXOTERE (5.7)
- Asthenia (5.12)

----------ADVERSE REACTIONS----------
Most common adverse reactions are infections, neutropenia, anemia, febrile neutropenia, hypersensitivity, thrombocytopenia, neuropathy, dysgeusia, dyspnea, constipation, anorexia, nail disorders, fluid retention, asthenia, pain, nausea, diarrhea, vomiting, mucositis, alopecia, skin reactions, myalgia (6)

Other adverse reactions, including serious adverse reactions have been reported (6)

To report SUSPECTED ADVERSE REACTIONS, contact sanofi-aventis U.S. LLC at 1-800-663-1610 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*

----------DRUG INTERACTIONS----------
- Compounds that induce, inhibit, or are metabolized by P450-3A4 (7)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling

Revised: 09/28/07

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed

FULL PRESCRIBING INFORMATION

WARNING

The incidence of treatment-related mortality associated with TAXOTERE therapy is increased in patients with abnormal liver function, in patients receiving higher doses, and in patients with non-small cell lung carcinoma and a history of prior treatment with platinum-based chemotherapy who receive TAXOTERE as a single agent at a dose of 100 mg/m^2 ***[see Warnings and Precautions (5.1)].***

TAXOTERE should generally not be given to patients with bilirubin > upper limit of normal (ULN), or to patients with SGOT and/or SGPT >1.5 x ULN concomitant with alkaline phosphatase >2.5 x ULN. Patients with elevations of bilirubin or abnormalities of transaminase concurrent with alkaline phosphatase are at increased risk for the development of grade 4 neutropenia, febrile neutropenia, infections, severe thrombocytopenia, severe stomatitis, severe skin toxicity, and toxic death. Patients with isolated elevations of transaminase >1.5 x ULN also had a higher rate of febrile neutropenia grade 4 but did not have an increased incidence of toxic death. Bilirubin, SGOT or SGPT, and alkaline phosphatase values should be obtained prior to each cycle of TAXOTERE therapy and reviewed by the treating physician.

TAXOTERE therapy should not be given to patients with neutrophil counts of <1500 cells/mm^3. In order to monitor the occurrence of neutropenia, which may be severe and result in infection, frequent blood cell counts should be performed on all patients receiving TAXOTERE.

Severe hypersensitivity reactions characterized by generalized rash/erythema, hypotension and/or bronchospasm, or very rarely fatal anaphylaxis, have been reported in patients who received the recommended 3-day dexamethasone premedication. Hypersensitivity reactions require immediate discontinuation of the TAXOTERE infusion and administration of appropriate therapy ***[see Warnings and Precautions (5.2)]***. TAXOTERE must not be given to patients who have a history of severe hypersensitivity reactions to TAXOTERE or to other drugs formulated with polysorbate 80 ***[see Contraindications (4)]***.

Severe fluid retention occurred in 6.5% (6/92) of patients despite use of a 3-day dexamethasone premedication regimen. It was characterized by one or more of the following events: poorly tolerated peripheral edema, generalized edema, pleural effusion requiring urgent drainage, dyspnea at rest, cardiac tamponade, or pronounced abdominal distention (due to ascites) ***[see Warnings and Precautions (5.10)].***

1. INDICATIONS AND USAGE

1.1 Breast Cancer

- TAXOTERE is indicated for the treatment of patients with locally advanced or metastatic breast cancer after failure of prior chemotherapy.
- TAXOTERE in combination with doxorubicin and cyclophosphamide is indicated for the adjuvant treatment of patients with operable node-positive breast cancer.

1.2 Non-Small Cell Lung Cancer

- TAXOTERE as a single agent is indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of prior platinum-based chemotherapy.
- TAXOTERE in combination with cisplatin is indicated for the treatment of patients with unresectable, locally advanced or metastatic non-small cell lung cancer who have not previously received chemotherapy for this condition.

1.3 Prostate Cancer

- TAXOTERE in combination with prednisone is indicated for the treatment of patients with androgen independent (hormone refractory) metastatic prostate cancer.

1.4 Gastric Adenocarcinoma

- TAXOTERE in combination with cisplatin and fluorouracil is indicated for the treatment of patients with advanced gastric adenocarcinoma, including adenocarcinoma of the gastroesophageal junction, who have not received prior chemotherapy for advanced disease.

1.5 Head and Neck Cancer

- TAXOTERE in combination with cisplatin and fluorouracil is indicated for the induction treatment of patients with locally advanced squamous cell carcinoma of the head and neck (SCCHN).

2. DOSAGE AND ADMINISTRATION

TAXOTERE (docetaxel) Injection Concentrate should be administered under the supervision of a qualified physician experienced in the use of antineoplastic agents. Appropriate management of complications is possible only when adequate diagnostic and treatment facilities are readily available.

2.1 Breast Cancer

- The recommended dose of TAXOTERE is 60-100 mg/m^2 administered intravenously over 1 hour every 3 weeks.
- In the adjuvant treatment of operable node-positive breast cancer, the recommended TAXOTERE dose is 75 mg/m^2 administered 1-hour after doxorubicin 50 mg/m^2 and cyclophosphamide 500 mg/m^2 every 3 weeks for 6 courses. Prophylactic G-CSF may

be used to mitigate the risk of hematological toxicities ***[see Dosage Adjustments During Treatment (2.7)]***.

2.2 Non-Small Cell Lung Cancer

- For treatment after failure of prior platinum-based chemotherapy, TAXOTERE was evaluated as monotherapy, and the recommended dose is 75 mg/m^2 administered intravenously over 1 hour every 3 weeks. A dose of 100 mg/m^2 in patients previously treated with chemotherapy was associated with increased hematologic toxicity, infection, and treatment-related mortality in randomized, controlled trials ***[see Boxed Warning, Dosage Adjustments During Treatment (2.7), Warnings and Precautions (5), Clinical Studies (14)]***.
- For chemotherapy-naïve patients, TAXOTERE was evaluated in combination with cisplatin. The recommended dose of TAXOTERE is 75 mg/m^2 administered intravenously over 1 hour immediately followed by cisplatin 75 mg/m^2 over 30-60 minutes every 3 weeks ***[see Dosage Adjustments During Treatment (2.7)]***.

2.3 Prostate cancer

- For hormone-refractory metastatic prostate cancer, the recommended dose of TAXOTERE is 75 mg/m^2 every 3 weeks as a 1 hour intravenous infusion. Prednisone 5 mg orally twice daily is administered continuously ***[see Dosage Adjustments During Treatment (2.7)]***.

2.4 Gastric adenocarcinoma

- For gastric adenocarcinoma, the recommended dose of TAXOTERE is 75 mg/m^2 as a 1 hour intravenous infusion, followed by cisplatin 75 mg/m^2, as a 1 to 3 hour intravenous infusion (both on day 1 only), followed by fluorouracil 750 mg/m^2 per day given as a 24-hour continuous intravenous infusion for 5 days, starting at the end of the cisplatin infusion. Treatment is repeated every three weeks. Patients must receive premedication with antiemetics and appropriate hydration for cisplatin administration ***[see Dosage Adjustments During Treatment (2.7)]***.

2.5 Head and Neck Cancer

Patients must receive premedication with antiemetics, and appropriate hydration (prior to and after cisplatin administration). Prophylaxis for neutropenic infections should be administered. All patients treated on the TAXOTERE containing arms of the TAX323 and TAX324 studies received prophylactic antibiotics.

- Induction chemotherapy followed by radiotherapy (TAX323)

  For the induction treatment of locally advanced inoperable SCCHN, the recommended dose of TAXOTERE is 75 mg/m^2 as a 1 hour intravenous infusion followed by cisplatin 75 mg/m^2 intravenously over 1 hour, on day one, followed by fluorouracil as a continuous intravenous infusion at 750 mg/m^2 per day for five days. This regimen is administered every 3 weeks for 4 cycles. Following chemotherapy, patients should receive radiotherapy. ***[see Dosage Adjustments During Treatment (2.7)]***.

- Induction chemotherapy followed by chemoradiotherapy (TAX324)

  For the induction treatment of patients with locally advanced (unresectable, low surgical cure, or organ preservation) SCCHN, the recommended dose of TAXOTERE is 75 mg/m^2 as a 1 hour intravenous infusion on day 1, followed by cisplatin 100 mg/m^2 administered as a 30-minute to 3 hour infusion, followed by fluorouracil 1000 mg/m^2/day as a continuous infusion from day 1 to day 4. This regimen is administered every 3 weeks for 3 cycles. Following chemotherapy, patients should receive chemoradiotherapy ***[see Dosage Adjustments During Treatment (2.7)]***.

2.6 Premedication Regimen

- All patients should be premedicated with oral corticosteroids (see below for prostate cancer) such as dexamethasone 16 mg per day (e.g., 8 mg BID) for 3 days starting 1 day prior to TAXOTERE administration in order to reduce the incidence and severity of fluid retention as well as the severity of hypersensitivity reactions ***[see Boxed Warning, Warnings and Precautions (5)]***.
- For hormone-refractory metastatic prostate cancer, given the concurrent use of prednisone, the recommended premedication regimen is oral dexamethasone 8 mg, at 12 hours, 3 hours and 1 hour before the TAXOTERE infusion ***[see Warnings and Precautions (5)]***.

2.7 Dosage Adjustments During Treatment

- Breast Cancer

Patients who are dosed initially at 100 mg/m^2 and who experience either febrile neutropenia, neutrophils <500 cells/mm^3 for more than 1 week, or severe or cumulative cutaneous reactions during TAXOTERE therapy should have the dosage adjusted from 100 mg/m^2 to 75 mg/m^2. If the patient continues to experience these reactions, the dosage should either be decreased from 75 mg/m^2 to 55 mg/m^2 or the treatment should be discontinued. Conversely, patients who are dosed initially at 60 mg/m^2 and who do not experience febrile neutropenia, neutrophils <500 cells/mm^3 for more than 1 week, severe or cumulative cutaneous reactions, or severe peripheral neuropathy during TAXOTERE therapy may tolerate higher doses. Patients who develop ≥grade 3 peripheral neuropathy should have TAXOTERE treatment discontinued entirely.

- Combination Therapy with TAXOTERE in the Adjuvant Treatment of Breast Cancer

TAXOTERE in combination with doxorubicin and cyclophosphamide should be administered when the neutrophil count is ≥1,500 cells/mm^3. Patients who experience febrile neutropenia should receive G-CSF in all subsequent cycles. Patients who continue to experience this reaction should remain on G-CSF and have their TAXOTERE dose reduced to 60 mg/m². Patients who experience Grade 3 or 4 stomatitis should have their TAXOTERE dose decreased to 60 mg/m². Patients who experience severe or cumulative cutaneous reactions or moderate neurosensory signs and/or symptoms during TAXOTERE therapy should have their dosage of TAXOTERE

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