For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

Abridged Prescribing Information

TAXOTERE®

Docetaxel Injection I.P.

COMPOSITION: TAXOTERE® 20mg/1ml vial (Docetaxel 20mg/ml) & TAXOTERE® 80mg/4ml vial (Docetaxel 80mg/4ml)
THERAPEUTIC INDICATIONS: 1) Breast Cancer (adjuvant and metastatic) 2) Non-Small Cell Lung Cancer 3) Ovarian Cancer 4) Prostate Cancer 5) Gastric Adenocarcinoma including adenocarcinoma of the gastroesophageal junction 6) Head & neck Cancer
DOSAGE AND ADMINISTRATION: Pre-medication consisting of oral dexamethasone 16mg/day for 3 days starting 1 day prior to docetaxel administration can be used. In case of prostate cancer the recommended premedication is oral dexamethazone 8mg, 12, 3 and 1 hour before docetaxel infusion. Prophylactic G-CSF may be used to mitigate the risk of haematological toxicity. Docetaxel is generally administered as 1-hour infusion every 3 weeks.
Breast Cancer: In adjuvant treatment of operable node-positive and node negative breast cancer, recommended dose is 75mg/m^2 administered 1-hour after doxorubicin 50mg/m^2 and cyclophosphamide 500mg/m^2 every 3 weeks for 6 cycles. For Adjuvant treatment of operable breast cancer whose tumors overexpress HER2: ***AC TH:*** AC (cycles 1-4): doxorubicin (A) 60 mg/m² followed by cyclophosphamide (C) 600 mg/m² administered every three weeks for 4 cycles. TH (cycles 5-8): docetaxel (T) 100 mg/m² administered every three weeks for 4 cycles, and trastuzumab (H) administered weekly as per schedule. ***TCH***: TCH (cycles 1-6): docetaxel (T) 75 mg/m² and carboplatin (C) at AUC of 6 mg/mL/min administered every three weeks and trastuzumab (H) administered weekly.
Metastatic breast cancer: In first line treatment docetaxel 75mg/m^2 is administered in combination with doxorubicin 50mg/m^2.
Combination with trastuzumab: Docetaxel dose is 100mg/m^2 every 3 weeks with trastuzumab administered weekly.
For 2nd line treatment docetaxel dosage is 100mg/m^2 as single agent.
Combination with capecitabine - Docetaxel 75mg/m^2 every 3 weeks with oral capecitabine 1250mg/m^2 twice daily (within 30 minutes after meal) for 2 weeks, followed by 1 week rest period.
Non-Small cell lung cancer: Docetaxel 75mg/m^2, followed by cisplatin 75mg/m^2 over 30-60 minutes or carboplatin (AUC 6mg/ml/min) over 30-60min. For treatment after failure of prior platinum-based therapy, docetaxel 75mg/m^2 is given as single agent.
Ovarian Cancer: As second line treatment, recommended dosage of docetaxel is 100 mg/m^2 as a single agent.
Prostate Cancer: In hormone refractory metastatic prostate cancer docetaxel is administered as 75mg/m^2 every 3 weeks and prednisone or prednisolone 5mg orally, twice daily is administered continuously.
Gastric Cancer: In case of advanced gastric and gastroesophageal junction adenocarcinoma for those who have not received prior chemotherapy docetaxel is administered, 75 mg/m^2 as a 1 hour infusion followed by cisplatin 75 mg/m^2 as a 1-3 hour infusion (both on day one only) followed by 5-flurouracil 750 mg/m^2 per day given as 24-hour continuous infusion for 5 days. Treatment repeated every 3 weeks for 4 cycles.
Head and Neck cancer: For the induction treatment for locally advanced inoperable squamous cell carcinoma of the head and neck (SCCHN) the recommended dose is 75 mg/m^2 as a 1 hour infusion followed by cisplatin 75mg/m^2 over 1 hour on day one, followed by 5-fluorouracil as a continuous infusion at 750 mg/m^2 per day for 5 days. To be administered every 3 weeks for 4 cycles. Following chemotherapy, patients should receive radiotherapy. - For the induction treatment of patients with locally advanced squamous cell carcinoma of the head and neck, the recommended dose of 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 5-fluorouracil 1000 mg/m2/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.
SAFETY RELATED INFORMATION
Contraindications: Severe hypersensitivity to the drug or polysorbate 80; patients with baseline neutrophil counts of <1500/mm^3; pregnancy; severe liver impairment. Contraindications for other drugs also apply when combined with docetaxel.
Precautions: Administration of corticosteroid therapy before docetaxel administration reduces the incidence and severity of fluid retention and hypersensitivity reactions. ***Neutropenia*****:** Frequent monitoring of complete blood counts. Retreatment with docetaxel to be started when neutrophil recover to $\geq$ 1500cells/mm^3. ***Hypersensitivity reactions*****:** Severe hypotension, bronchospasm or generalized rash/erythema or very rarely fatal anaphylaxis has been reported. Hypersensitivity reactions require immediate discontinuation of docetaxel. Patients with severe hypersensitivity should not be rechallenged with docetaxel. ***Cutaneous Reactions*****:** Localized skin erythema of the extremities with oedema followed by desquamation has been observed. ***Fluid Retention:*** Patients with pleural and pericardial effusion and ascites should be monitored closely. ***Liver impairment:*** Higher risk of developing severe adverse reactions such as toxic deaths including sepsis and GI haemorrhage, febrile neutropenia, infections, thrombocytopenia, stomatitis and asthenia in patients treated with docetaxel at 100mg/m^2 as single agent with transaminase levels greater than 1.5 times the ULN concurrent with serum alkaline phosphatase levels greater than 2.5 times the ULN. For patients with serum bilirubin levels >ULN and / or ALT and AST>3.5 times the ULN concurrent with serum alkaline phosphatase levels > 6 times the ULN, no dose reduction can be recommended and docetaxel should not be used unless strictly indicated. No data on patients with hepatic impairment. ***Nervous System:*** Severe neurosensory signs and / or symptoms have been observed and require reduction of dose. ***Cardiac Toxicity:*** Heart failure observed in patients receiving Taxotere in combination with trastuzumab, particularly following anthracycline containing chemotherapy. May be moderate or severe and has been associated with death. ***Eye disorders:*** Cystoid macular oedema (CMO) has been reported in patients treated with docetaxel, as well as with other taxanes; if diagnosed, docetaxel treatment should be discontinued and appropriate treatment initiated. ***Leukemia:*** In the treatment of adjuvant breast cancer, the risk of delayed myelodysplasia or myeloid leukaemia requires haematological follow-up. ***Interactions:*** Concomitant use of Taxotere® with strong CYP3A4 inhibitors should be avoided. ***Excipients:*** The amount of ethanol in Taxotere® may impair the ability to drive or use machines.. ***Elderly:*** Patients equal to or greater than 60 years of age, treated with Taxotere and capecitabine combination therapy showed an increase in treatment related adverse events, serious adverse events and early withdrawals from treatment due to adverse events compared to patients less than 60 years of age.
Pregnancy & Lactation: Contraindicated in pregnancy. It is not known whether docetaxel is excreted in human milk. Because of the potential for adverse reactions in nursing infants, breast feeding must be discontinued for the duration of docetaxel therapy.
Adverse Reactions: Very common ones include neutropenia (in pts who did not receive G-CSF), hypersensitivity reactions, cutaneous reactions, fluid retention, neurological, gastrointestinal effects, hepatic, alopecia, asthenia, arthralgias, myalgias, dyspnea, generalized or localized pain, including chest pain, without any cardiac or respiratory involvement, infusion site reactions, renal and urinary disorders, Cases of hyponatraemia have been reported, mostly associated with dehydration, vomiting and pneumonia.Cases of permanent alopecia (frequency not known) have been reported.

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