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, unless contraindicated, can be used , For metastatic castration-resistant prostate cancer, given and metastatic hormone-sensitive prostate cancer, irrespective of the concurrent use of prednisone or prednisolone, the recommended premedication regimen 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: Adjuvant 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 6courses. For Adjuvant treatment of operable breast cancer whose tumors overexpress HER2 the recommended dose is: ***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: Metastatic castration-resistant prostate cancer - Recommended dose of docetaxel 75mg/m^2 every 3 weeks and prednisone or prednisolone 5mg orally, twice daily is administered continuously. Metastatic hormone-sensitive prostate cancer - Recommended dose of docetaxel is 75 mg/m2 every 3 weeks for 6 cycles. Prednisone or prednisolone
10 mg orally daily may be administered continuously
GastricAdenocarcinoma: For gastric adenocarcinoma recommended dose is, 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, starting at the end of cisplatin infusion. Treatment repeated every 3 weeks. Patients must receive premedication with antiemetics and appropriate hydration for cisplatin administration. Prophylactic G-CSF should be used to mitigate the risk of hematological toxicities
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. 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: . An oral corticosteroid such as dexamethasone 16 mg per day for 3 days starting one day prior to docetaxel administration, unless contraindicated, can reduce the incidence and severity of fluid retention as well as the severity of hypersensitivity reactions. The pretreatment regimen for prostate cancer is oral dexamethasone 8 mg, 12 hours, 3 hours and 1 hour before the docetaxel infusion. ***Neutropenia*****:** Frequent monitoring of complete blood counts. Retreatment with docetaxel to be started when neutrophil recover to $\geq$ 1500cells/mm^3. **Gastrointestinal reactions:** Caution is recommended for patients with neutropenia, particularly at risk for developing gastrointestinal complications. Enterocolitis could develop at any time, and could lead to death as early as on the first day of onset. Patients should be closely monitored for early manifestations of serious gastrointestinal toxicity. ***Hypersensitivity reactions*****:** Severe hypotension, generalized rash/erythema, bronchospasm 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. Patients who have previously experienced a hypersensitivity reaction to paclitaxel may develop a potentially fatal hypersensitivity reaction to docetaxel ***Cutaneous Reactions*****:** Localized skin erythema of the extremities with edema followed by desquamation has been observed. Severe Cutaneous Adverse Reactions (SCARs) such as Stevens-Johnson Syndrome (SJS) , Toxic Epidermal Necrolysis (TEN) and Acute Generalized Exanthematous Pustulosis (AGEP) have been reported in association with docetaxel treatment. Patients should be informed about the signs and symptoms of serious skin manifestations and monitored closely. In case SCARs are observed,treatment discontinuation should be considered. ***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. This may be moderate to severe and has been associated with death. Ventricular arrhythmia including ventricular tachycardia (sometimes fatal) has been reported in patients treated with docetaxel in combination regimens including doxorubicin, 5-fluorouracil and/ or cyclophosphamide. Baseline cardiac assessment is recommended***. Eye disorders:*** Cystoid macular edema (CME) 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.**Second primary malignancies:** Have been reported when docetaxel was given in combination with anticancer treatments, associated with second primary malignancies. Second primary malignancies (including acute myeloid leukemia, myelodysplastic syndrome, non-Hodgkin lymphoma and renal cancer) may occur several months or years after docetaxel-containing therapy. Patients should be monitored for second primary malignancies . ***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: Cases of Cutaneous lupus erythematosus**,** Erythema multiforme, severe cutaneous adverse reaction such as Stevens Johnson Syndrome, toxic epidermal necrolysis, acute generalized exanthematous pustulosis, Scleroderma-like changes, Cases of Cystoid Macular Oedema (CMO), Disseminated intravascular coagulation (DIC) often in association with sepsis, or multiorgan failure , Renal insufficiency and renal failure, hyponatraemia electrolyte imbalance, Hypokalaemia, hypomagnesaemia, and hypocalcaemia have been reported . **Rare Cases:** Anaphylactic Shock, Dehydration, pulmonary edema,dehydration as a consequence of gastrointestinal events including enterocolitis and gastrointestinal perforation, ileus, intestinal obstruction, convulsion, venous thromboembolic events myocardial infarction, ototoxicity, hearing disorders and/or hearing loss, lacrimation with or without conjunctivitis, transient visual disturbances, Respiratory, thoracic, mediastinal disorders, **Very Rare Cases:** , Hypersensitivity reaction resulted in a fatal outcome in patients who received premedication, Hepatitis sometimes fatal primarily in patients with pre-existing liver disorders,acute myeloid leukaemia, myelodysplastic syndrome**.** lacrimal duct obstruction resulting in excessive tearing have been reported primarily in patients receiving other anti-tumor agents concomitantly. **Frequency not known:** Hypersensitivity reactions with potential fatal outcome, who previously experienced hypersensitivity reactions to paclitaxel, permanent alopecia, Enterocolitis, including colitis, ischemic colitis, and neutropenic enterocolitis with potential fatal outcome, Ventricular arrhythmia including ventricular tachycardia sometimes fatal, has been reported in patients treated with docetaxel in combination regimens including doxorubicin, 5-fluorouracil and/ or cyclophosphamide , Injection site recall reaction, Second primary malignancies including non-Hodgkin lymphoma and renal cancer. **Frequency Uncommon**: Acute myeloid leukemia, myelodysplastic syndrome

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