פייזר פי אף אי פרמצבטיקה ישראל בע"מ
רח' שנקר 9, ת.ד. 12133
הרצליה פיתוח, ישראל 46725
טל: 972-9-9700500 פקס: 972-9-9700501

ינואר 2024

רופא/ה, רוקח/ת נכבד/ה,

ברצוננו להודיעך על עדכונים בעלונים לרופא של התכשיר **DOCETAXEL HOSPIRA® 10 MG/ML**

צורת מינון: Solution for infusion
חוזק: Docetaxel 10MG/ML
התוויה:

Breast cancer
Docetaxel in combination with doxorubicin and cyclophosphamide is indicated for the adjuvant treatment of patients with operable node-positive breast cancer.
Docetaxel in combination with doxorubicin is indicated for the treatment of patients with locally advanced or metastatic breast cancer who have not previously received cytotoxic therapy for this condition.
Docetaxel monotherapy is indicated for the treatment of patients with metastatic breast cancer after failure of cytotoxic therapy. Previous chemotherapy should have included an anthracycline or an alkylating agent.
Docetaxel in combination with trastuzumab is indicated for the treatment of patients with metastatic breast cancer whose tumors over-express HER2 and who previously have not received chemotherapy for metastatic disease.
Docetaxel in combination with capecitabine is indicated for the treatment of patients with metastatic breast cancer after failure of cytotoxic chemotherapy. Previous therapy should have included an anthracycline.
Doxorubicin and cyclophosphamide followed by docetaxel in combination with trastuzumab (AC-TH) is indicated for the adjuvant treatment of patients with HER2 over-expressing, node-positive or high-risk node-negative, breast cancer.
Docetaxel in combination with trastuzumab, and carboplatin (TCH) is indicated for the adjuvant treatment of patients with HER2 over-expressing, node-positive or high-risk node-negative, breast cancer.
Non-small cell lung cancer: Docetaxel is indicated for the treatment of patients with advanced non-small cell lung carcinoma.
Ovarian cancer: Docetaxel is indicated for treatment of metastatic carcinoma of the ovary after failure of first line or subsequent chemotherapy.
Prostate cancer: Docetaxel in combination with prednisone or prednisolone is indicated for the treatment of patients with hormone refractory metastatic prostate cancer.
Esophageal cancer: Docetaxel for the treatment of esophageal cancer.
Gastric cancer: Docetaxel for the treatment of advanced gastric cancer.
Head and neck (SCCHN):
Docetaxel as monotherapy in the treatment of patients with recurrent and/or metastatic squamous cell carcinoma of the head and neck after failure of a previous chemotherapy regimen.
Docetaxel in combination with cisplatin and 5-fluorouracil is indicated for the induction treatment of patients with locally advanced squamous cell carcinoma of the head and neck.

להלן העדכונים העיקריים בעלון לרופא:

Posology and method of administration
Ovarian Cancer
The recommended dose of Docetaxel is 100 mg/m^2 administered as a one-hour infusion every 3 weeks. When used in combination, Docetaxel is administered at the recommended dose of 75 mg/m^2.

Special warnings and precautions for use
Gastrointestinal reactions
Caution is recommended for patients with neutropenia, particularly at risk for developing gastrointestinal complications. Although majority of cases occurred during the first or second cycle of docetaxel containing regimen, 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
… Patients who have developed severe hypersensitivity reactions should not be re-challenged with docetaxel. Patients who have previously experienced a hypersensitivity reaction to paclitaxel may be at risk to develop hypersensitivity reaction to docetaxel, including more severe hypersensitivity reaction. These patients should be closely monitored during initiation of docetaxel therapy.

Cutaneous reactions
…Severe Cutaneous Adverse Reactions (SCARs) such as Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN) and Acute Generalized Exanthematous Pustulosis (AGEP) have been reported with docetaxel treatment. Patients should be informed about the signs and symptoms of serious skin manifestations and closely monitored. If signs and symptoms suggestive of these reactions appear discontinuation of docetaxel should be considered.

Cardiac toxicity
…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.

Tumour lysis syndrome
Tumour lysis syndrome has been reported with docetaxel after the first or the second cycle. Patients at risk of tumour lysis syndrome (e.g. with renal impairment, hyperuricemia, bulky tumour, rapid progression) should be closely monitored. Correction of dehydration and treatment of high uric acid levels are recommended prior to initiation of treatment.

Others
Women of childbearing potential must use contraceptive measures during treatment and for 2 months after cessation of treatment with docetaxel. Men must use contraceptive measures during treatment and for 4 months after cessation of treatment with docetaxel.

Excipient information
Ethanol content
20mg/2 mL vial
Each 2 mL vial of concentrate contains 364 mg anhydrous ethanol (see section 2), which is equivalent to less than 10 mL beer or 4 mL wine.
80 mg/8 mL vial
Each 8 mL vial of concentrate contains 1455 mg anhydrous ethanol (see section 2), which is equivalent to less than 37 mL beer or 15 mL wine.
160 mg/16 mL vial
Each 16 mL vial of concentrate contains 2911 mg anhydrous ethanol (see section 2), which is equivalent to less than 73 mL beer or 30 mL wine.
An example of ethanol exposure based on maximum single daily dose (see section 4.2) is as follows:
Administration of 18 mL of this medicinal product to an adult weighing 70 kg would result in exposure to 46.8 mg/kg of ethanol which may cause a rise in blood alcohol concentration (BAC) of 7.8 mg/100 mL.
For comparison, for an adult drinking a glass of wine or 500 mL of beer, the BAC is likely to be about 50 mg/100 mL.
Co-administration with medicines containing e.g. propylene glycol or ethanol may lead to accumulation of ethanol and induce adverse effects, particularly in young children with low or immature metabolic capacity.

Fertility, pregnancy and lactation
Women of childbearing potential/Contraception in males and females
…Due to the genotoxic risk of docetaxel, women of childbearing potential must use effective method of contraception during treatment and for 2 months after cessation of treatment with docetaxel. Men must use effective contraception during treatment and for 4 months after cessation of treatment with docetaxel.

…

Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed. The side effects of the product may impair the ability to drive or use machines. Therefore, patients should be warned of the potential impact of the side effects of this medicinal product on the ability to drive or use machines, and be advised not to drive or use machines if they experience these side effects during treatment.

Undesirable effects

Description of selected adverse reactions in breast cancer for docetaxel 100 mg/m^2 single agent

Blood and lymphatic system disorders

Not known: Leucopenia

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Post-marketing experience

Neoplasms benign, malignant and unspecified (incl. cysts and polyps)

Second primary malignancies (frequency not known), including non-Hodgkin lymphoma have been reported in association with docetaxel when used in combination with other anticancer treatments known to be associated with second primary malignancies.

…

Immune system disorders

…Hypersensitivity reactions (frequency not known) have been reported with docetaxel in patients who previously experienced hypersensitivity reactions to paclitaxel.

…

Cardiac disorders

…Ventricular arrhythmia including ventricular tachycardia (frequency not known), sometimes fatal, has been reported in patients treated with docetaxel in combination regimens including doxorubicin, 5-fluorouracil and/ or cyclophosphamide.

Gastrointestinal disorders

Rare cases of enterocolitis, including colitis, ischemic colitis, and neutropenic enterocolitis, have been reported with a potential fatal outcome (frequency not known).

…

Skin and subcutaneous tissue disorders

Cases of cutaneous lupus erythematosus, bullous eruptions such as erythema multiforme, and severe cutaneous adverse reactions such as Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN) and Acute Generalized Exanthematous Pustulosis (AGEP) have been reported with docetaxel. Scleroderma-like changes usually preceded by peripheral lymphoedema have been reported with docetaxel. Cases of permanent alopecia (frequency not known) have been reported.

…

Metabolism and nutrition disorders

Cases of electrolyte imbalance have been reported. Cases of hyponatraemia have been reported, mostly associated with dehydration, vomiting and pneumonia. Hypokalaemia, hypomagnesaemia, and hypocalcaemia were observed, usually in association with gastrointestinal disorders and in particular with diarrhoea. Tumour lysis syndrome, potentially fatal, has been reported (frequency not known).

Musculoskeletal disorder

Myositis has been reported with docetaxel (frequency not known).

השינויים המודגשים ברקע צהוב מהווים החמרה. כמו כן, בוצעו שינויים נוספים הכוללים תוספת מידע, השמטת מידע ועדכוני נוסח שאינם מהווים החמרה אשר עודכנו ביתר הסעיפים בעלון.
העלון לרופא נשלח למשרד הבריאות לצורך פרסומו במאגר התרופות שבאתר משרד הבריאות: https://data.health.gov.il/drugs/index.html#!/byDrug לחילופין, לקבלת עלון מלא מודפס ניתן לפנות לחברת פייזר פי אף אי פרמצבטיקה ישראל בע"מ רח' שנקר 9, ת.ד. 12133, הרצליה פיתוח, 46725.

בברכה,
גילי קבשה
רוקחת ממונה