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 2018

רופא/ה, רוקח/ת נכבד/ה,

ברצוננו להודיעך על עדכון בעלון לרופא של התכשיר Cytosar 1 G

המרכיב הפעיל:

Cytarabine 1 g/vial

Indicated for:

Induction and maintenance of remission in acute myelocytic leukemia of adults and children.
Treatment of other leukemias.

קו תחתי משמעו תוספת טקסט, קו חוצה משמעו מחיקת טקסט, הדגשה משמעה החמרה.

להלן העדכונים העיקריים בעלון לרופא:

Contraindications

Therapy with cytarabine should not be considered in patients with pre-existing drug-induced bone marrow suppression, unless the clinician feels that such management offers the most hopeful alternative for the patient. Cytarabine should not be used in the management of non-malignant disease, except for immunosuppression.

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Special warnings and precautions for use

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Warnings:

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The main toxic effect of cytarabine is bone marrow suppression with leukopenia, thrombocytopenia, anaemia, megaloblastosis and reduced reticulocytes. Less serious toxicity includes nausea, vomiting, diarrhoea and abdominal pain, oral ulceration, and hepatic dysfunction (see section 4.8).

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Cytarabine has been shown to be carcinogenic in animals. The possibility of a similar effect should be borne in mind when designing the long-term management of the patient.

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Hepatic and/or Renal Function: The human liver apparently detoxifies a substantial fraction of an administered dose of cytarabine. In particular, patients with renal or hepatic function impairment may have a higher likelihood of CNS toxicity after high-dose treatment with cytarabine. Use the drug with caution and at reduced dose in patients whose liver function is poor.

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Neurological: Cases of severe neurological adverse reactions that ranged from headache to paralysis, coma and stroke-like episodes have been reported mostly in juveniles and adolescents given intravenous cytarabine in combination with intrathecal methotrexate.

The safety of this drug for use in infants is not established.

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Pancreatitis: Cases of pancreatitis have been observed with the induction of cytarabine.

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Interaction with other medicinal products and other forms of interaction

5-Fluorocytosine should not be administered with Cytarabine as the therapeutic efficacy of 5-Fluorocytosine has been shown to be abolished during such therapy.

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Methotrexate: Intravenous cytarabine given concomitantly with intrathecal methotrexate may increase the risk of severe neurological adverse reactions such as headache, paralysis, coma and stroke like episodes (see section 4.4).

Fertility, pregnancy and lactation

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This product should not normally be administered to patients who are pregnant or to mothers who are breast-feeding.

Effects on ability to drive and use machines

Cytarabine has no effect on intellectual function or psychomotor performance. Nevertheless, patients receiving chemotherapy may have an impaired ability to drive or operate machinery and should be warned of the possibility and advised to avoid such tasks if so affected.

Undesirable effects

Summary of the safety profile (see also section 4.4)

Most frequent adverse reactions include nausea, vomiting, diarrhoea, fever, rash, anorexia, oral and anal inflammation or ulceration, and hepatic dysfunction.

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Adverse Reactions Table

Infections and Infestations:	
Very common	Sepsis, pneumonia, infection[a]
Frequency not known	Injection site cellulitis, liver abscess
Blood and Lymphatic System Disorders:	
Very common	Bone marrow failure, thrombocytopenia, anaemia, anaemia megaloblastic, leukopenia, reticulocyte count decreased
Immune System Disorders:	
Frequency not known	Anaphylactic reaction, allergic oedema
Metabolism and Nutrition Disorders:	
Frequency not known	Decreased appetite
Nervous System Disorders:	
Frequency not known	Neurotoxicity, neuritis, dizziness, headache
Eye Disorders:	
Frequency not known	Conjunctivitis[b]
Cardiac Disorders:	
Frequency not known	Pericarditis, sinus bradycardia
Vascular Disorders:	

Frequency not known	Thrombophlebitis
Respiratory, Thoracic and Mediastinal Disorders:	
Frequency not known	Dyspnoea, oropharyngeal pain
Gastrointestinal Disorders:	
Very common	Stomatitis, mouth ulceration, anal ulcer, anal inflammation, diarrhoea, vomiting, nausea, abdominal pain
Frequency not known	Pancreatitis, oesophageal ulcer, oesophagitis
Hepatobiliary Disorders:	
Very common	Hepatic function abnormal
Frequency not known	Jaundice
Skin and Subcutaneous Tissue Disorders:	
Very common	Alopecia, rash
Common	Skin ulcer
Frequency not known	Palmar-plantar erythrodysaesthesia syndrome, urticaria, pruritus, ephelides
Musculoskeletal, Connective Tissue and Bone Disorders:	
Very common	Cytarabine syndrome
Renal and Urinary Disorders:	
Frequency not known	Renal impairment, urinary retention
General Disorders and Administration Site Conditions:	
Very common	Pyrexia
Frequency not known	Chest pain, injection site reaction[c]
Investigations:	
Very common	Biopsy bone marrow abnormal, blood smear test abnormal
[a]may be mild, but can be severe and at times fatal [b]may occur with rash and may be hemorrhagic with high dose therapy [c]pain and inflammation at subcutaneous injection site	

Adverse reactions reported in association with high dose therapy (see section 4.4) are included in the following table:

Adverse Reactions Table (High Dose Therapy)

Infections and Infestations:	
Frequency not known	Liver abscess, sepsis
Psychiatric Disorders:	
Frequency not known	Personality change[a]
Nervous System Disorders:	
Very common	Cerebral disorder, cerebellar disorder, somnolence
Frequency not known	Coma, convulsion, peripheral motor neuropathy, peripheral sensory neuropathy

Eye Disorders:	
Very common	Corneal disorder
Cardiac Disorders:	
Frequency not known	Cardiomyopathy[b], sinus bradycardia
Respiratory, Thoracic and Mediastinal Disorders:	
Very common	Acute respiratory distress syndrome, pulmonary oedema
Gastrointestinal Disorders:	
Common	Necrotising colitis
Frequency not known	Gastrointestinal necrosis, gastrointestinal ulcer, pneumatosis intestinalis, peritonitis
Hepatobiliary Disorders:	
Frequency not known	Liver injury, hyperbilirubinaemia
Skin and Subcutaneous Tissue Disorders:	
Common	Skin exfoliation,

[a]personality change was reported in association with cerebral and cerebellar dysfunction.
[b]with subsequent death

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Overdose

Cessation of therapy, followed by management of ensuing bone marrow depression including whole blood or platelet transfusion and antibiotics as required.

העלון המעודכן נשלח למשרד הבריאות לצורך פרסומו במאגר התרופות שבאתר משרד הבריאות:
http://www.health.gov.il/units/pharmacy/trufot/index.asp

לחילופין, לקבלת עלון מלא מודפס ניתן לפנות לחברת פייזר פי אף אי פרמצבטיקה ישראל בע"מ
שנקר 9, ת.ד. 12133
הרצליה פיתוח, 46725.

בברכה,
אורטל עבודי
רוקחת ממונה