נובמבר 2020

רופא/ה, רוקח/ת נכבד/ה,

הנדון: עדכון עלון לרופא של התכשיר
בוסולפקס BUSULFEX

מרכיב פעיל:

Busulfan 60mg/10ml

צורת מינון ומתן: Solution for injection, IV

התוויה מאושרת:
For use in combination with other chemotherapeutic agents and/or radiotherapy as a conditioning regimen prior to hematopoietic progenitor cell transplantation.

חברת צמל ביו-פארמה בע"מ מבקשת להודיעכם על העדכונים הבאים בעלון לרופא של התכשיר.
בהודעה זו מצוינים השינויים המהווים החמרה או חידוש בלבד, והן מסומנים בקו תחתי.

WARNINGS
… Busulfan may be a human carcinogen. Secondary malignancy has been reported in patients treated with BUSULFEX. Several cases of leukemia have occurred 5-8 years following oral busulfan treatment. Busulfan may also cause cellular dysplasia.

BUSULFEX may cause temporary or permanent infertility in females and males. Ovarian suppression and amenorrhea commonly occur in premenopausal women undergoing chronic, low-dose busulfan therapy for chronic myelogenous leukemia. Sterility, azoospermia, and testicular atrophy have been reported in male patients.
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Pregnancy: Busulfan can cause fetal harm when administered to a pregnant woman. There are no adequate and well-controlled studies in pregnant women. BUSULFEX should not be administered to pregnant women or women who may possibly be pregnant. If BUSULFEX is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus. Women of childbearing potential should be advised to use effective contraception during

and up to 6 months after treatment. BUSULFEX may damage spermatozoa and testicular tissue, resulting in possible genetic fetal abnormalities. Men treated with BUSULFEX are advised not to father a child during and up to 6 months after treatment.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for tumorigenicity shown for busulfan in human and animal studies, breast-feeding should be discontinued during treatment with BUSULFEX. The safety of BUSULFEX in nursing women has not been established...

Hepatic Insufficiency: BUSULFEX has not been administered to patients with hepatic insufficiency. However, patients who have received prior radiation therapy, greater than or equal to three cycles of chemotherapy, or a prior progenitor cell transplant may be at an increased risk of developing hepatic veno-occlusive disease with the recommended BUSULFEX dose and regimen (see ADVERSE REACTIONS).

PRECAUTIONS

Information for Patients: …. Patients of reproductive potential should be advised of the potential risk to a fetus and the need to use effective contraception during and after treatment with BUSULFEX, and to inform their healthcare professional of a known or suspected pregnancy. Patients should be informed of the possibility of developing low blood cell counts and the need for hematopoietic progenitor cell infusion. They should also be instructed to immediately report to their healthcare professional if fever develops.
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To detect hepatotoxicity, which may herald the onset of hepatic veno-occlusive disease, serum transaminases, alkaline phosphatase, and bilirubin should be evaluated daily through transplant day 28. Cardiac function should be monitored regularly in patients receiving BUSULFEX.

ADVERSE REACTIONS

The following additional adverse events have been spontaneously reported during the post-marketing use of BUSULFEX: .. tooth hypoplasia.
Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

העלון המאושר נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות www.health.gov.il וניתן לקבלו מודפס על ידי פנייה לבעל הרישום, צמל ביו-פארמה בע"מ, טלפון: 073-7151111.

בברכה,
צמל ביו-פארמה