פייזר פי אף אי פרמצבטיקה ישראל בע"מ
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אוקטובר 2022

רופא/ה, רוקח/ת נכבד/ה,
ברצוננו להודיעך על עדכון בעלון לרופא של :

ZAVEDOS 10 MG

Indications:

Antimitotic and cytotoxic agent.
Acute non-limphocytic Leukemia (ANLL) in adults for remission induction in untreated patients or for remission induction in relapsed or refractory patients.
Acute limphocytic leukemia (ALL) as second line treatment in adults and children.

להלן העדכונים העיקריים בעלון לרופא:

4.4 Special warnings and precautions for use

Reproductive System
Idarubicin can cause genotoxicity. Male and female patients. treated with idarubicin hydrochloride are advised to adopt effective contraceptive measures during therapy and for a period after treatment.
Men treated with idarubicin hydrochloride are advised, if appropriate and available, to seek advice on sperm preservation due to the possibility of irreversible infertility caused by the therapy (see section 4.6).
Patients desiring to have children after completion of therapy should be advised to discuss with an appropriate specialist first.

4.6 Fertility, pregnancy and lactation

Fertility

Idarubicin can induce chromosomal damage in human spermatozoa. For this reason, males undergoing treatment with idarubicin should use effective contraceptive methods up to 3 months after treatment (see section 4.4).

Pregnancy
There are limited amount of data from the use of idarubicin in pregnant women. Studies in animals have shown reproductive toxicity (see section 5.3).

~~The embryotoxic potential of idarubicin has been demonstrated in both in vitro and in vivo studies. However, there are no adequate and well-controlled studies in pregnant women~~

Idarubicin should not be used during pregnancy unlessonly if the potential benefit justifies the potential risk to the foetus. The patient should be informed of the potential hazard to the foetus.

Women of childbearing potential/ Contraception in males and females
Women of child bearing potential should be advised not to become pregnant~~ during treatment and adopt adequate contraceptive measures during therapy as suggested by a physician.~~

~~Idarubicin should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus. The patient should be informed of the potential hazard to the foetus. Patients desiring to have children after completion of therapy should be advised to obtain genetic counselling first if appropriate and available.~~
and to use effective contraception during treatment with idarubicin and for at least 6.5 months after the last dose. Men with female partners of childbearing potential should be advised to use effective contraception during treatment with idarubicin and for at least 3.5 months after the last dose (see section 4.4).

Breast-feeding
It is not known whether idarubicin or its metabolites are excreted in human milk.
~~Mothers should not breast-feed during treatment with idarubicin hydrochloride.~~

As other anthracyclines are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from idarubicin, women should be advised not to breastfeed during treatment with idarubicin and for at least 14 days after the last dose.

Fertility
Idarubicin can induce chromosomal damage in human spermatozoa. For this reason, males undergoing treatment with idarubicin should use effective contraceptive methods for at least 3.5 months after the last dose (see section 4.4). Both men and women should seek advice on fertility preservation before treatment.

5.2 Pharmacokinetic properties

~~Hepatic and renal impairment~~
~~The pharmacokinetics of idarubicin in patients with hepatic and/or renal impairment have not been fully evaluated. It is expected that in patients with moderate or severe hepatic dysfunction, the metabolism of idarubicin may be impaired and lead to higher systemic drug levels. The disposition of idarubicin may also be affected by renal impairment. Therefore, a dose reduction should be considered in patients with hepatic and/or renal impairment (see section 4.4) and idarubicin is contraindicated in patients with severe hepatic and/or renal failure (see section 4.3).~~

6.6 Special precautions for disposal and other handling

The following protective recommendations are given due to the toxic nature of this substance:

- This product should be handled only by personnel who have been trained in the safe handling of such preparations.
- Pregnant staff should be excluded from working with this drug.
- Personnel handling Zavedos® should wear protective clothing: goggles, gowns and disposable gloves and masks.
- ~~A designated area should be defined for reconstitution (preferably under a laminar flow system). The work surface should be protected by disposable, plastic-backed, absorbent paper.~~
- All items used for administration or cleaning, including gloves, should be placed in high risk, waste disposal bags for high temperature incineration.
- The reconstituted solution is hypotonic and the recommended administration procedure described below must be followed.

השינויים המודגשים ברקע צהוב מהווים החמרה. כמו כן, בוצעו שינויים נוספים הכוללים תוספת מידע, השמטת מידע ועדכוני נוסח שאינם מהווים החמרה.
העלונים לרופא ולצרכן נשלחו למשרד הבריאות לצורך פרסומם במאגר התרופות שבאתר משרד הבריאות:
https://israeldrugs.health.gov.il/#!/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,
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