ניאופרם ישראל
קבוצת ניאופרם

רופא/ה, רוקח/ת נכבד/ה,

אברקסן אבקה להכנת תרחיף לעירוי למתן תוך-ורידי
Abraxane Powder for Suspension for I.V Infusion

- העלון לרופא עודכן בינואר 2019
- בהודעה זו מצוינים השינויים המהווים החמרה וכן שינויים נוספים שאינם החמרה
- טקסט שהתווסף מסומן בקו תחתי, טקסט שהוסר מסומן בקו חוצה

החומר הפעיל: Paclitaxel 100 mg/vial

להלן נוסח ההתוויה המאושר לתכשיר:

Abraxane monotherapy is indicated for the treatment of metastatic breast cancer in adult patients who have failed first-line treatment for metastatic disease and for whom standard, anthracycline containing therapy is not indicated.

Abraxane in combination with gemcitabine is indicated for the first-line treatment of adult patients with metastatic adenocarcinoma of the pancreas.

Abraxane in combination with carboplatin is indicated for the first-line treatment of non-small cell lung cancer in adult patients who are not candidates for potentially curative surgery and/or radiation therapy.

העדכונים העיקריים בעלון לרופא נעשו בסעיפים הבאים:

4.6 Fertility, pregnancy and lactation

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Pregnancy

There are very limited data on the use of paclitaxel in human pregnancy. Paclitaxel is suspected to cause serious birth defects when administered during pregnancy. Studies in animals have shown reproductive toxicity (see section 5.3). Women of childbearing potential should have a pregnancy test prior to starting treatment with Abraxane. Abraxane should not be used in pregnancy, and in women of childbearing potential not using effective contraception, unless the clinical condition of the mother requires treatment with paclitaxel.

Breast-feeding

Paclitaxel and/or its metabolites were excreted into the milk of lactating rats (see section 5.3). It is not known if paclitaxel is excreted in human milk. Because of potential serious adverse reactions in breast-feeding infants, Abraxane is contraindicated during lactation. Breast-feeding must be discontinued for the duration of therapy.

Fertility

Abraxane induced infertility in male rats (see section 5.3). Based on findings in animals, male and female fertility may be compromised. Male patients should seek advice on conservation of sperm prior to treatment because of the possibility of irreversible infertility due to therapy with Abraxane.

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4.8 Undesirable effects

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There have been reports of tumour lysis syndrome during treatment with Abraxane.

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5.3 Preclinical safety data

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Paclitaxel at doses below the human therapeutic dose was associated with low fertility when administered prior and during mating in male and female rats and foetal toxicity in rats. Animal studies with Abraxane showed non-reversible, toxic effects on the male reproductive organs at clinically relevant exposure levels.

Paclitaxel and/or its metabolites were excreted into the milk of lactating rats. Following intravenous administration of radiolabelled paclitaxel to rats on days 9 to 10 postpartum, concentrations of radioactivity in milk were higher than in plasma and declined in parallel with the plasma concentrations.

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6.1 Shelf life

Unopened vials

The expiry date of the product is indicated on the packaging materials.

Stability of reconstituted suspension in the vial

Chemical and physical in use stability has been demonstrated for ~~8~~ 24 hours at 2°C-8°C in the original carton, protected from light.

Stability of the reconstituted suspension in the infusion bag

Chemical and physical in use stability has been demonstrated for ~~8~~ 24 hours at 2°C-8°C followed by 4 hours at ~~not above~~ 25°C, protected from light.~~.~~

However, from a microbiological point of view, unless the method of reconstituting and filling of the infusion bags precludes the risks of microbial contamination, the product should be used immediately after reconstitution and filling of the infusion bags.

If not used immediately, in-use storage times and conditions are the responsibility of the user.

The total combined storage time of reconstituted medicinal product in the vial and in the infusion bag when refrigerated and protected from light is 24 hours. This may be followed by storage in the infusion bag for 4 hours below 25°C.

העלון לרופא נשלח למשרד-הבריאות לצורך העלאתו למאגר התרופות שבאתר משרד-הבריאות וניתן לקבלו מודפס על ידי פנייה לבעל הרישום: ניאופרם סיינטיפיק בע"מ, רח' השילוח 6, ת.ד. 7063 פתח-תקווה, טל: 03-9373753.

בברכה,

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