רופא/ה נכבד/ה,
רוקח/ת נכבד/ה,

תאריך: ינואר 2024

Phenasen

חברת ביומד-יר בע"מ מבקשת להודיע על עדכונים בעלון לרופא של התכשיר שבנדון.

צורת המתן של התכשיר
Solution for injection

מרכיב פעיל
arsenic trioxide 1 mg/1ml

התכשיר מיועד להתוויות:

Phenasen 1 mg/ml is indicated for induction of remission, and consolidation in adult patients with:

- Newly diagnosed low-to-intermediate risk acute promyelocytic leukaemia (APL) (white blood cell count, ≤ 10 x 103/µl) in combination with all-trans-retinoic acid (ATRA).
- Relapsed/refractory acute promyelocytic leukaemia (APL) (Previous treatment should have included a retinoid and chemotherapy) characterised by the presence of the t(15;17) translocation and/or the presence of the Pro-Myelocytic Leukaemia/Retinoic-Acid-Receptor-alpha (PML/RAR-alpha) gene.

The response rate of other acute myelogenous leukaemia subtypes to arsenic trioxide has not been examined.

עדכונים בעלון לרופא נעשו בסעיפים הבאים:
החמרות מסומנות בצהוב, תוספת מידע בקו תחתון ומחיקת מידע מסומנת ~~בקו אמצעי~~.

4.3 Contraindications
Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
Phenasen is contraindicated in pregnancy or when there is a possibility of pregnancy (see Section 4.6 Fertility, pregnancy and lactation).

4.6 Fertility, pregnancy and lactation
Contraception in males and females
Due to the genotoxic risk of arsenic compounds (see section 5.3), women of childbearing potential and men must use effective contraceptive measures during treatment with Phenasen 1 mg/ml and for 6 months following completion of treatment.

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Men should use effective contraceptive measures and be advised to not father a child while receiving Phenasen 1 mg/ml and for 3 months following completion of treatment.

Breast-feeding

Arsenic is excreted in human milk. Because of the potential for serious adverse reactions in ~~breast-feeding~~ nursing infants and children from ~~Phenasen 1 mg/ml,~~arsenic trioxide, breastfeeding must be discontinued prior to and throughout administration and for two weeks after the last dose.

6.3 Shelf life

Unopened vial

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

After first opening

Once opened the product should be used immediately.

After dilution

-Following its withdrawal from the vial, and immediate dilution with 100 to 250 ml of glucose 50 mg/ml (5 %) solution for injection or sodium chloride 9 mg/ml (0.9 %) solution for injection, ~~in intravenous solutions,~~ Phenasen 1 mg/ml ~~is~~ was demonstrated to be chemically and physically stable for 168 hours at both 15°C-30°C and ~~72 hours at~~ refrigerated (2°C-8°C) temperatures.

העלון לצרכן במתכונת עלון לרופא מפורסם במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס על ידי פניה לבעל הרישום, חברת ביומד-יר, רחוב היסמין 28 תל-מונד, או בטלפון 09-7746004

בברכה,

גלי קיסר

רוקחת ממונה