פייזר פי אף אי פרמצבטיקה ישראל בע"מ
רח' שנקר 9, ת.ד. 12133
הרצליה פיתוח, ישראל 46725
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דצמבר 2025

רופא/ה, רוקח/ת נכבד/ה,
ברצוננו להודיעך על עדכון בעלון לרופא של **Unasyn 1.5gr :**

Indications:
Sulbactam sodium/ampicillin sodium IM/IV is indicated for the treatment of infections due to susceptible beta-lactamase producing strains of microorganisms in the following conditions:
1) Skin and Skin Structure Infections.
2) Intra-Abdominal Infections.
3) Gynecological Infections.

להלן העדכונים העיקריים בעלון לרופא:

Description

Each 1.5 g vial contains ampicillin 1 gr as the sodium salt plus 0.5 g sulbactam as the sodium salt) (equivalent to 1.063 g ampicillin sodium and 0.547 g sulbactam sodium) contains approximately 115 mg of sodium.

Directions For Use
1.5 g Standard Vials:

a) Reconstitute the vials with Sterile Water for Injection:

TABLE 4.

UNASYN Vial Size	Volume of Sterile Water for Injection for Reconstitution
1.5 g	3.2 mL

- The reconstituted UNASYN solutions will have a total concentration of 375 mg/mL (ampicillin concentration of 250 mg/mL and sulbactam concentration of 125 mg/mL).
- The resultant volume post reconstitution for the 1.5 g vials is approximately 4 mL.

b) For intravenous infusion, immediately dilute with a suitable parenteral diluent (see Table 5) to yield solutions containing a total concentration between 3 mg/mL to 45 mg/mL of UNASYN (ampicillin concentration of 2 mg/mL to 30 mg/mL and sulbactam concentration of 1 mg/mL to 15 mg/mL).

Storage of Diluted UNASYN Solutions
Following dilution of reconstituted UNASYN, at the specified concentrations, the diluted solutions may be stored in the infusion bags based on conditions outlined in Table 5. After the indicated time periods, discard any unused portions of solutions.

~~Preparation for Intravenous Use~~
~~1.5 g Bottle: UNASYN® sterile powder in piggyback units may be reconstituted directly to the desired concentrations using any of the following parenteral diluents. Reconstitution of UNASYN®, at the specified concentrations, with these diluents provide stable solutions for the time periods indicated in the following table: (After the indicated time periods, any unused portions of solutions should be discarded).~~

~~If piggyback bottles are unavailable, standard vials of UNASYN® sterile powder may be used. Initially, the vials may be reconstituted with Sterile Water for Injection to yield solutions containing 375 mg UNASYN® per mL (250 mg ampicillin plus 125 mg sulbactam per mL). An appropriate volume should then be immediately diluted with a suitable parenteral diluent to yield solutions containing 3 to 45 mg UNASYN® per mL (2 to 30 mg ampicillinplus 1 to 15 mg sulbactam per mL).~~

השינויים המודגשים ברקע צהוב מהווים החמרה. כמו כן, בוצעו שינויים נוספים הכוללים תוספת מידע, השמטת מידע ועדכוני נוסח שאינם מהווים החמרה. העלונים המעודכנים זמינים באתר משרד הבריאות.

https://www.old.health.gov.il/units/pharmacy/trufot/index.asp?safa=h
לחילופין, לקבלת עלון מלא מודפס ניתן לפנות לחברת פייזר פי אף אי פרמצבטיקה ישראל בע"מ, שנקר 9, ת.ד. 12133
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בברכה,
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