



אוקטובר 2024

פיזר פי אף אי פרמצבטיקה ישראל בע"מ
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רופא/ה, רוקח/ת נכבד/ה,
ברצוננו להודיעך על עדכון בעלון לרופא של **Unasyn 1.5gr, Unasyn 3.0gr**

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

3 g of UNASYN® (2 g ampicillin as the sodium salt plus 1 g sulbactam as the sodium salt) parenteral contains approximately 230 mg (10 mEq) of sodium.

Unasyn 3.0 Gr-

This medicinal product contains approximately 230.23 mg of sodium per vial, equivalent to 11.51% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

Warnings

Severe Cutaneous Adverse Reactions

UNASYN® may cause severe skin reactions, such as toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), **drug reaction with eosinophilia and systemic symptoms (DRESS)**, dermatitis exfoliative, erythema multiforme, and Acute generalized exanthematous pustulosis (AGEP). If patients develop a skin rash they should be monitored closely and UNASYN® discontinued if lesions progress (see **CONTRAINDICATIONS** and **ADVERSE REACTIONS** sections).

Adverse reactions

Infections and Infestations: Clostridioides difficile- associated diarrhea (see **WARNINGS** sections).

Gastrointestinal Disorders: Abdominal pain, cholestatic hepatitis, cholestasis, hyperbilirubinemia, jaundice, abnormal hepatic function, melena, gastritis, stomatitis, dyspepsia, and black "hairy" tongue and ~~Clostridium difficile~~ associated diarrhea (see **CONTRAINDICATIONS** and **WARNINGS** sections).

Musculoskeletal and Connective Tissue Disorders: Arthralgia

Skin and Subcutaneous Tissue Disorders: Toxic epidermal necrolysis, Stevens-Johnson syndrome, **drug reaction with eosinophilia and systemic symptoms (DRESS)**, angioedema, Acute generalized exanthematous pustulosis (AGEP), erythema multiforme, exfoliative dermatitis, urticaria (see **CONTRAINDICATIONS** and **WARNINGS** sections), and linear IgA bullous dermatosis.

Dosage ad administration

The recommended adult dosage of UNASYN® is 1.5 g (1 g ampicillin as the sodium salt plus 0.5 g sulbactam as the sodium salt) to ~~3 g (2 g ampicillin as the sodium salt plus 1 g sulbactam as the sodium salt)~~ every six hours. This ~~1.5 to 3 g range represents the total of ampicillin content plus the sulbactam content of UNASYN®, and corresponds to a range of 1 g ampicillin/0.5 g sulbactam to 2 g ampicillin/1 g sulbactam.~~ The total dose of sulbactam should not exceed 4 grams per day.

TABLE 3

UNASYN® Dosage Guide for Patients with Renal Impairment

Creatinine Clearance (mL/min/1.73m ²)	Ampicillin/Sulbactam Half-Life (Hours)	Recommended UNASYN® Dosage
≥30	1	1.5-3 g q 6h-q 8h
15-29	5	1.5-3 g q 12h
5-14	9	1.5-3g q 24h

Directions for Use

TABLE 5

UNASYN® Vial Size	Volume of Diluent to be Added	Withdrawal Volume*
1.5 g	3.2 mL	4.0 mL
3.0 g	6.4 mL	8.0 mL

*There is sufficient excess present to allow withdrawal and administration of the stated volumes.

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 הרצליה פיתוח, 46725.

בברכה,
אורטל עבודי
רוקחת ממונה