

ציפרו-טבע 2מ"ג/מ"ל תמיסה לאינפוזיה

Cipro-Teva 2mg/ml

Contains: Ciprofloxacin (as lactate) 2mg/ 1ml

עדכונים בעלון לרופא

התוויה כפי שאושרה בתעודת הרישום:**Adults:**

Broad spectrum antibiotic for infections caused by ciprofloxacin sensitive pathogens.

Children and adolescents:

- Broncho-pulmonary infections in cystic fibrosis caused by *Pseudomonas aeruginosa*
- Complicated urinary tract infections and pyelonephritis
- Inhalation anthrax (post-exposure prophylaxis and curative treatment)

Ciprofloxacin may also be used to treat severe infections in children and adolescents when there is no other alternative.

Treatment should be initiated only by physicians who are experienced in the treatment of cystic fibrosis and/or severe infections in children and adolescents.

ברצוננו להודיע שהעלון לרופא עודכן. בפירוט שלהלן כלולים העדכונים העיקריים בלבד (תוספות מסומנות באדום והסרות מידע כטקסט מחוק):**4.4 Special warnings and precautions for use****Cardiac disorders**

Since ciprofloxacin is associated with cases of QT prolongation (see section 4.8), caution should be exercised when treating patients at risk for torsade de pointes arrhythmia.

QT interval prolongation

Caution should be taken when using fluoroquinolones, including ciprofloxacin, in patients with known risk factors for prolongation of the QT interval such as, for example:

[...]

NaCl load

In patients for whom sodium intake is of medical concern (e.g. patients with congestive heart failure, renal failure, nephrotic syndrome), the additional sodium load should be taken into account (see section 2).

Sodium

This medicinal product contains 707.70 mg sodium per dose, equivalent to 35.39% of the WHO recommended daily intake for sodium for adults.

The maximum daily dose of this product is equivalent to 106.16 % of the WHO recommended maximum daily intake for sodium for adults.

Appropriate consideration should be taken when administering this product to children.

Ciprofloxacin is considered high in sodium. This should be particularly taken into account for those on a low sodium diet.

[...]

4.5 Interactions with other medicinal products and other forms of interaction

Ciprofloxacin, like other fluoroquinolones, should be used with caution in patients receiving drugs known to prolong the QT interval (e.g. Class IA and III anti arrhythmics, tricyclic antidepressants, macrolides, antipsychotics) (see section 4.4).

[...]

6.4 Special precautions for storage**Unopened:**

Store below 25°C.

Keep the bottles in the outer carton in order to protect from light.



Do not refrigerate or freeze.

Bottles after removing from carton:

To be used immediately after removing from carton.

Since Cipro-Teva 2 mg/ml Solution for infusion is light-sensitive, the bottles should always be stored in the outer container.

No special precautions are required during the normal 60 minute infusion period.

[...]

6.6 Special precautions for disposal and other handling

Intravenous infusion:

[...]

- Cipro-Teva 2mg/mL is compatible with the following commonly used infusion fluids: Ringer's solution, Ringer lactate solution, 0.9% Sodium chloride solution, Dextrose 5% and Dextrose 10% solutions, Fructose 10% solution, Sodium chloride 0.45% + Dextrose 5% solution and Sodium chloride 0.225% + Dextrose 5% solution. All solutions are stable for 48 hours below 25°C, with the only exception of the mixture of Cipro-Teva 2mg/mL with Ringer's solution, which is stable for 12 hours below 25°C. **Unless compatibility is proven, the infusion solution should always be administered separately.**

[...]

העלונים נשלחו לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות
וניתן לקבלו מודפס ע"י פניה לחברת טבע. <http://www.israeldrugs.health.gov.il>