ינואר 2024

רופא/ה נכבד/ה,
רוקח/ת נכבד/ה,

חברת פרופארם בע"מ מודיעה על העדכונים הבאים בעלון לרופא של התכשיר:

CIPROFLOXACIN I.V ALTAN 2 MG/ML
ציפרופלוקסצין I.V אלטן 2 מ"ג/מ"ל

חומר פעיל: CIPROFLOXACIN 2 MG/ML
צורת מינון: SOLUTION FOR INFUSION
צורת מתן: I.V.

עדכונים בעלון לרופא

<u>התויה כפי שאושרה בתעודת הרישום:</u>

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.

<u>ברצונינו להודיע שהעלון לרופא עודכן, בפירוט שלהלן כלולים העדכונים העיקריים בלבד(תוספות /שינויים מסומנים באדום והחמרות/מידע חדש על רקע צהוב):</u>

1. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each bag with 100 ml of solution for infusion contains 200 mg of ciprofloxacin
Each bag with 200 ml of solution for infusion contains 400 mg of ciprofloxacin
Excipients with known effect:
[…]

4. CLINICAL PARTICULARS

[…]

4.3 Contraindications

- Hypersensitivity to the active ~~substance~~ ingredient, to other quinolones or to ~~any~~ one of the excipients (~~listed in~~ see section 6.1).

[…]

4.4 Special warnings and precautions for use

Intra-abdominal infections
There are limited data available on the efficacy of ciprofloxacin in the treatment of post-surgical intra-abdominal infections.
[…]

Inhalational anthrax
Use in humans is has been based on *in-vitro* susceptibility data and on animal experimental data together with limited human data. Treating physicians should refer to the national and/or international consensus documents regarding the treatment of anthrax
[…]

Broncho-pulmonary infections in with cystic fibrosis:
Clinical trials have included children and adolescents aged 5-17 years. More limited experience is available in treating children between 1 and 5 years of age.
[…]

Hypersensitivity
Hypersensitivity and allergic reactions, including anaphylaxisctic and anaphylactoid reactions, may occur following a single dose (see section 4.8) and may be life-threatening. If such reaction occurs, ciprofloxacin should must be discontinued and an adequate medical treatment is required.
[…]

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:
- congenital long QT syndrome
- concomitant use of drugs that are known to prolong the QT interval (e.g. Class IA and III anti-arrhythmics, tricyclic antidepressants, macrolides, antipsychotics)
- uncorrected electrolytes imbalance (e.g. hypokalaemia, hypomagnesaemia)
- cardiac disease (e.g. heart failure, myocardial infarction, bradycardia)

Elderly patients and women may be more sensitive to QTc-prolonging medications. Therefore, caution should be taken when using fluoroquinolones, including ciprofloxacin, in these populations.
(See section 4.2 Elderly patients, section 4.5, section 4.8, section 4.9).
[…]

Glucose-6-phosphate dehydrogenase deficiency:
Haemolytic reactions have been reported with the use of ciprofloxacin in patients with a glucose-6-phosphate dehydrogenase deficiency. Ciprofloxacin should be avoided in these patients unless the potential benefit is considered to outweigh the possible risk. In this case, potential occurrence of haemolysis should be monitored.*Resistance*:
[…]

Methotrexate
The concomitant use of ciprofloxacin with and methotrexate is not recommended (see section 4.5).
[…]

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

Glucose
This medicine contains 0.05 g of glucose per ml of solution for infusion. This must be taken into account in the treatment of patients with diabetes mellitus.

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. PHARMACEUTICAL PARTICULARS

6.2 Incompatibilities

The~~is~~ medicinal product ~~solution should~~ must not be mixed with other ~~solutions or medicines~~ medicinal products except those mentioned in section 6.6. ~~See also "Special precautions for disposal and other handling".~~

Unless compatibility with other solutions/drugs has been confirmed, the infusion solution must always be administered separately. The visual signs of incompatibility are e.g. precipitation, clouding, and discolouration.

Incompatibility appears with all infusion solutions/drugs that are physically or chemically unstable at the pH of the solutions (e.g. penicillins, heparin solutions), especially in combination with solutions adjusted to an alkaline pH (pH of ciprofloxacin solutions: 3.9 - 4.5).

6.3 Shelf life

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

From a microbiological point of view, the product should be used immediately once opened (see section 6.4).

[…]

6.6 Special precautions for disposal and other handling

[…]

Any unused solution should be disposed of in accordance with local requirements.

העלון לרופא מצורף להודעה זו וכן נשלח לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות.

ניתן לקבל את העלון מודפס ע"י פניה לבעל הרישום, חברת פרופארם בע"מ, בטל' 04-6294242 או במייל: orders@propharm.co.il.

בברכה,

מירי חזן

רוקחת ממונה