



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

#### 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.

#### ברצונינו להודיע שהעלון לרופא עודכן, בפירוט שלהלן כלולים העדכונים העיקריים בלבד (תוספות מסומנות באדום והסרות מידע כטקסט מחוק):

#### 4. CLINICAL PARTICULARS

##### 4.1 Therapeutic indications

Ciprofloxacin solution for infusion is indicated for the treatment of the following infections.

Special attention should be paid to available information on resistance to ciprofloxacin before commencing therapy.

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

##### Adults

~~Broad spectrum antibiotic for infections caused by ciprofloxacin sensitive pathogens.~~

- Lower respiratory tract infections due to Gram-negative bacteria
  - exacerbations of chronic obstructive pulmonary disease. In exacerbation of chronic obstructive pulmonary disease Ciprofloxacin should be used only when it is considered inappropriate to use other antibacterial agents that are commonly recommended for the treatment of these infections.
  - broncho-pulmonary infections in cystic fibrosis or in bronchiectasis
  - pneumonia
- Chronic suppurative otitis media
- Acute exacerbation of chronic sinusitis especially if these are caused by Gram negative bacteria
- Urinary tract infections
  - Acute pyelonephritis
  - Complicated pyelonephritis
  - Bacterial prostatitis
- Genital tract infections
  - Epididymo-orchitis including cases due to susceptible Neisseria gonorrhoeae
  - Pelvic inflammatory disease including cases due to susceptible Neisseria gonorrhoeae

Propharm Ltd., P.O.B. 4046, Zichron Yaacov 30900, Israel, Tel. +972-4-6294242, Fax. +972-4-6392049

Email: [info@propharm.co.il](mailto:info@propharm.co.il) , Web: [www.propharm.co.il](http://www.propharm.co.il)



- Infections of the gastro-intestinal tract (e.g. travellers' diarrhoea)
- Intra-abdominal infections
- Infections of the skin and soft tissue caused by Gram-negative bacteria
- Malignant external otitis
- Infections of the bones and joints
- Inhalation anthrax (post-exposure prophylaxis and curative treatment)

Ciprofloxacin may be used in the management of neutropenic patients with fever that is suspected to be due to a bacterial infection

Children and adolescents:

- Broncho-pulmonary infections ~~due to in cystic fibrosis caused by *Pseudomonas aeruginosa*~~ in patients with cystic fibrosis
- Complicated urinary tract infections and acute 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~~ this is considered to be necessary.

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

#### 4.4 Special warnings and precautions for use

[...]

##### Inhalational anthrax

Use in humans ~~has been~~ is 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.

##### ~~Children and adolescents~~ Paediatric population:

The use of ciprofloxacin in children and adolescents should follow available official guidance. Ciprofloxacin treatment should be initiated only by physicians who are experienced in the treatment of cystic fibrosis and/or severe infections in children and adolescents.

[...]

##### Psychiatric reactions

Psychiatric reactions may occur even after first administration of ciprofloxacin. In rare cases, depression or psychosis can progress to suicidal ideations/thoughts culminating in attempted suicide or completed suicide. ~~If depression, psychotic reactions, suicide-related thoughts or behaviour~~ In the occurrence of such cases, ciprofloxacin should be discontinued.

## 6. PHARMACEUTICAL PARTICULARS

### 6.5 Nature and contents of container

Flexible bag of laminated PVC. Bags containing 100 ml or 200 ml of solution for infusion. The packaging is of 50 bags of 100 ml or 20 bags of 200 ml. It's possible that not all the presentations are commercialized.

The solution is clear. ~~and colourless~~