

05.2025

**LEVOFLOXACIN FRESENIUS 5 MG/ML**  
SOLUTION FOR INFUSION

**לבופלוקססין פרזניוס 5 מ"ג/מ"ל**  
תמיסה לעירוי

רופא/ה, רוקח/ת נכבד/ה, ניאופרם (ישראל) 1996 בע"מ מבקשת להודיע על עדכון עלון לרופא של התכשיר שבנידון. העלון עודכן בתאריך 05/2025.

**ההתוויה המאושרת לתכשיר בישראל:**

Levofloxacin solution for infusion is indicated in adults for the treatment of the following infections:

- Acute pyelonephritis and complicated urinary tract infections
- Chronic bacterial prostatitis

In the below-mentioned infections levofloxacin should be used only when it is considered inappropriate to use other antibacterial agents that are commonly recommended for the treatment of these infections:

- Community-acquired pneumonia
- Complicated skin and soft tissue infections

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

**מקרא לעדכונים המסומנים:**

מידע שהוסר - מסומן בקו אדום חוצה **XXX**

תוספת - כתב **כחול**

תוספת החמרה - כתב **כחול** - מסומן בצהוב מרקר

בהודעה זו מצוינים העדכונים העיקריים בעלון לרופא, בעלון קיימים עדכונים נוספים.

**4.4. Special warnings and precautions for use**

(...)

*Prolonged, disabling and potentially irreversible serious adverse drug reactions*

(...)

**There are no pharmacological treatments established to be effective treatments of the symptoms of long lasting or disabling side effects associated with fluoroquinolones.** Levofloxacin Fresenius 5mg/ml should be discontinued immediately at the first signs or symptoms of any serious adverse reaction and patients should be advised to contact their prescriber for advice, **so that symptoms can be appropriately investigated and to avoid further exposure which could potentially worsen adverse reactions.**

(...)

**4.8. Undesirable effects**

System organ class	Common (≥1/100 to <1/10 )	Uncommon (≥1/1,000 to <1/100)	Rare (≥1/10,000 to <1/1,000)	Not known (cannot be estimated from available data)
(...)				
Musculoskeletal and connective tissue disorders *		Arthralgia Myalgia	Tendon disorders, <b>tendon rupture (e.g. Achilles tendon)</b> (see sections 4.3 and 4.4) including tendinitis (e.g. Achilles tendon) Muscular weakness which may be of special importance in patients with myasthenia gravis (see section 4.4)	Rhabdomyolysis <del>tendon rupture (e.g. Achilles tendon)</del> (see sections 4.3 and 4.4) Ligament rupture Muscle rupture Arthritis

(...)				
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\***Very rare cases** of (...) **depression**, fatigue, **psychiatric symptoms**, memory impairment, **sleep disorders**, (...).  
**A range of psychiatric symptoms may occur as part of these side effects, which may include, but are not necessarily limited to, sleep disorders, anxiety, panic attacks, confusion, or depression. There are no pharmacological treatments established to be effective treatments of the symptoms of long lasting or disabling side effects associated with fluoroquinolones. The frequency of these prolonged, disabling and potentially irreversible serious drug reactions cannot be estimated with precision using available data, but the reporting incidence from adverse drug reaction reports indicates the frequency is at minimum between 1/1,000 and 1/10,000 (corresponding to the Rare frequency category).**

למידע נוסף יש לעיין בעלון לרופא המעודכן אשר נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות.  
 כמו כן, ניתן לקבלו מודפס על ידי פניה לבעל הרישום: ניאופרם (ישראל) 1996 בע"מ, בניין ניאופרם, רח' השילוח 6, ת.ד. 7063, פתח תקווה 4917001. טלפון: 03-9373737, פקס: 03-9373770.

בברכה,  
 עוז וולך  
 רוקח ממונה של בעל הרישום