

03-2022

Levofloxacin Fresenius 5mg/ml

לבופלוקסין פרזניוס 5 מ"ג/ מ"ל

Solution for Infusion

חומר פעיל:

Levofloxacin(as hemihydrate) 5mg/ml

רופא/ה, רוקח/ת נכבד/ה,

- חברת ניאופרם (ישראל) 1996 בע"מ מבקשת להודיע על עדכון העלון לרופא של התכשיר Levofloxacin Fresenius 5mg/ml
- עלון התכשיר עודכן ב 03-2022
- בהודעה זו כלולים שינויי בטיחות מהותיים שמופיעים **בכחול** -טקסט חדש מופיע **בכחול** , טקסט שהוסר מופיע **באדום** עם **קו-חוצה**. טקסט שעבר מקום מופיע **בירוק**.

• **להלן נוסח ההתוויות המאושרות לתכשיר:**

In adults for whom intravenous therapy is considered to be appropriate, Levofloxacin Fresenius 5mg/ml solution for infusion is indicated for the treatment of the following infections when due to levofloxacin - susceptible micro-organisms:

- Community- acquired pneumonia,
- Complicated urinary tract infections including pyelonephritis,
- Skin and soft tissue infections.

עדכונים מהותיים נעשו בסעיפים הבאים בעלון לרופא:

4.4. Special warnings and precautions for use

Aortic aneurysm and dissection, and heart valve regurgitation/incompetence

Epidemiologic studies report an increased risk of aortic aneurysm and dissection particularly in elderly patients, and of aortic and mitral valve regurgitation after intake of fluoroquinolones, particularly in the older population.

Cases of aortic aneurysm and dissection, sometimes complicated by rupture (including fatal ones), and of regurgitation/incompetence of any of the heart valves have been reported in patients receiving fluoroquinolones (see section 4.8).

Therefore, fluoroquinolones should only be used after careful benefit-risk assessment and after consideration of other therapeutic options in patients with positive family history of aneurysm disease, or congenital heart valve disease or in patients diagnosed with pre-existing aortic aneurysm and/or aortic dissection, or heart valve disease or in presence of other risk factors or conditions predisposing for aortic aneurysm and dissection (e.g. Marfan syndrome, vascular Ehlers-Danlos syndrome, Takayasu arteritis, giant cell arteritis, Bechet's disease, hypertension, known atherosclerosis).

- for both aortic aneurysm and dissection and heart valve regurgitation / incompetence (e.g. connective tissue disorders such as Marfan syndrome, or Ehlers-Danlos syndrome, Turner

syndrome, Takayasu arteritis, giant cell arteritis, Behcet's disease, hypertension, rheumatoid arthritis) ~~known atherosclerosis~~ or additionally

- for aortic aneurysm and dissection (e.g. vascular disorders such as Takayasu arteritis or giant cell arteritis, or known atherosclerosis, or Sjogren syndrome) or additionally

- for heart valve regurgitation / incompetence (e.g. infective endocarditis)

The risk of aortic aneurysm and dissection, and their rupture may also be increased in patients treated concurrently with systemic corticosteroids.

In case of sudden abdominal, chest or back pain, patients should be advised to immediately consult a physician in an emergency department.

Patients should be advised to seek immediate medical attention in case of acute dyspnoea, new onset of heart palpitations, or development of oedema of the abdomen or lower extremities.

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Severe bullous reactions ~~Severe cutaneous adverse reactions~~

Severe cutaneous adverse reactions (SCARs) including toxic epidermal necrolysis (TEN : also known as Lyell's Syndrome), Cases of severe bullous skin reactions such as Stevens-Johnson syndrome (SJS) and drug reaction with eosinophilia and systemic symptoms (DRESS) which could be life threatening or fatal, or toxic epidermal necrolysis have been reported with levofloxacin (see section 4.8). Patients should be advised to contact their doctor immediately prior to continuing treatment if skin and/or mucosal reactions occur. At the time of prescription, patients should be advised of the signs and symptoms of severe skin reactions, and be closely monitored. If signs and symptoms suggestive of these reactions appear, levofloxacin should be discontinued immediately and an alternative treatment should be considered. If the patient has developed a serious reaction such as SJS, TEN or DRESS with the use of levofloxacin, treatment with levofloxacin must not be restarted in this patient at any time.

Dysglycaemia

As with all quinolones, disturbances in blood glucose, including both hypoglycaemia and hyperglycaemia have been reported, occurring more frequently in the elderly, usually in diabetic patients receiving concomitant treatment with an oral hypoglycemic agent (e.g., glibenclamide) or with insulin. Cases of hypoglycaemic coma have been reported. In diabetic patients, careful monitoring of blood glucose is recommended. (See section 4.8).

Levofloxacin treatment should be stopped immediately if a patient reports blood glucose disturbance and alternative nonfluoroquinolone antibacterial therapy should be considered

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Psychotic reactions

Psychotic reactions have been reported in patients receiving quinolones, including levofloxacin. In very rare cases these have progressed to suicidal thoughts and self-endangering behaviour-sometimes after only a single dose of levofloxacin (see section 4.8). In the event that the patient

develops these reactions, levofloxacin should be discontinued immediately at the first signs or symptoms of these reactions and patients should be advised to contact their prescriber for advice. Alternative nonfluoroquinolone antibacterial therapy should be considered, and appropriate measures instituted. Caution is recommended if levofloxacin is to be used in psychotic patients or in patients with history of psychiatric disease.

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)
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Endocrine disorders			Syndrome of inappropriate secretion of antidiuretic hormone (SIADH)	
Metabolism and nutrition disorders			Hypoglycaemia particularly in diabetic patients, (see section 4.4) Hypoglycaemic coma (see section 4.4)	Hyperglycaemia (see section 4.4) Hypoglycaemic coma
Psychiatric disorders *	Insomnia	Anxiety Confusional state Nervousness	Psychotic reactions (with e.g. hallucination, paranoia) Depression Agitation Abnormal dreams Nightmares, Delerium	Psychotic disorders with self-endangering behaviour including suicidal ideation or suicide attempt (see section 4.4)
Nervous system disorders *	Headache Dizziness	Somnolence Tremor Dysgeusia	Convulsion (see sections 4.3 and 4.4) Paraesthesia Memory impairment	Peripheral sensory neuropathy (see section 4.4) Peripheral sensory motor neuropathy (see section 4.4) Parosmia including anosmia Dyskinesia Extrapyramidal disorder Ageusia Syncope Benign intracranial hypertension

Skin and subcutaneous tissue disorders ^b		Rash Pruritus Urticaria Hyperhidrosis	<u>Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) (see section 4.4), Fixed drug eruption</u>	Toxic epidermal necrolysis Stevens-Johnson syndrome Erythema multiforme Photosensitivity reaction (see section 4.4) Leukocytoclastic vasculitis Stomatitis
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קיימים עדכונים נוספים . למידע נוסף יש לעיין בעלון לרופא המעודכן

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות ו ניתן לקבל 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