



Bundesamt für
Sicherheit im
Gesundheitswesen
BASG

Unternehmen/Frau/Herr
Organisationseinheit (optional)
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Unser Zeichen: PHV-105938755-A-261022-EUIM

PHV-issue: Levofloxacin (intravenous and oral use)

Sehr geehrte Damen und Herren,

Bitte beachten Sie die Coordination Group for Mutual Recognition and Decentralised Procedures Human (CMDh) Minutes for the meeting on 15-17 September 2026 bezüglich Levofloxacin (intravenous and oral use).

Bei Unklarheiten bezüglich der Implementierung oder wenn die Änderungen bereits aufgenommen worden sind, kontaktieren Sie uns bitte per E-Mail (pv-implementation@basg.gv.at).

Beachten Sie auch die aktuellen sicherheitsrelevanten Änderungen der Produktinformation unter: www.basg.gv.at/fuer-unternehmen/pharmakovigilanz/mustertexte

In der Begründung ist „**PHV-Issue: „Levofloxacin (intravenous and oral use)“**“ sowie die **Geschäftszahl (PHV-105938755-A-261022-EUIM)** anzugeben.

Mit freundlichen Grüßen
Für das Bundesamt

Ing. Veronika Heimlich BSc



Auszug aus dem Report from the CMDh meeting held on 15-17 September 2026

6.6. Other topics related to pharmacovigilance

6.6.1. Levofloxacin (DE/H/5119/001-003/II/118) / DE

The CMDh was informed about the outcome of the variation procedure DE/H/5119/001-003/II/118 for levofloxacin-containing medicinal products (intravenous and oral use). PRAC advice was sought during the procedure, which confirmed the updates to SmPC section 4.4, 4.7, 4.8 and 4.9 and the PL sections 2 and 4 to add encephalopathy as ADR. MAHs of products containing levofloxacin-containing medicinal products (intravenous and oral use) are requested to implement the below wording, via a type IB variation C.3.b. (new text **underlined and in bold**, deleted text ~~strike through~~):

SmPC

Section 4.4

Encephalopathy and myoclonus

Cases of **encephalopathy and** myoclonus have been reported in patients receiving levofloxacin (see sections 4.8 and 4.9). The risks of **encephalopathy and** myoclonus ~~is~~ **are** increased in older patients, and in patients with renal impairment if the dose of levofloxacin is not adjusted as per the creatinine clearance, **or in patients with pre-existing central nervous system disorders**. ~~Levofloxacin should be discontinued immediately at the first occurrence of~~ **If levofloxacin-associated encephalopathy and/or myoclonus are suspected, discontinuation of levofloxacin should be considered,** and appropriate treatment should be initiated.

Section 4.7

Tavanic has minor or moderate influence on the ability to drive and use machines. Some undesirable effects **such as encephalopathy,** (e.g. dizziness/vertigo, drowsiness, visual disturbances) may impair the patient's ability to concentrate and react, and therefore may constitute a risk in situations where these abilities are of special importance (e.g. driving a car or operating machinery).

Section 4.8

SOC Nervous system disorders

Frequency not known: **Encephalopathy**

Section 4.9

CNS effects **and signs of encephalopathy** including confusional state, convulsion, myoclonus, hallucination, and tremor have been observed in post marketing experience. **There is a higher risk of encephalopathy following overdose, particularly in elderly patients and patients with renal impairment.**

In the event of overdose, symptomatic treatment should be implemented. ECG monitoring should be undertaken, because of the possibility of QT interval prolongation. Antacids may be used for protection of gastric mucosa. Haemodialysis, including peritoneal dialysis and CAPD, are not effective in removing levofloxacin from the body. No specific antidote exists.

PL

2. What you need to know before you...

Warnings and precautions

[...]

when you are taking your medicine:

[...]

- If you start experiencing **episodes of light headedness, feeling confused, abnormal movements, fainting and seizures (symptoms of encephalopathy),** **or** sudden involuntary jerks, twitches of the muscles or muscle contractions **(symptoms of myoclonus)** - see a doctor straight away ~~as this could be signs of~~

~~myoclonus~~. Your doctor may need to stop treatment with levofloxacin and to start an appropriate treatment.

Driving and using machines

You may get side effects after taking/being given this medicine, including feeling dizzy, **feeling confused, abnormal movements, fainting, seizures**, sleepy, a spinning feeling (vertigo) or changes to your eyesight. Some of these side effects can affect you being able to concentrate and your reaction speed. If this happens, do not drive or carry out any work that requires a high level of attention.

4. Possible side effects

Tell your doctor if any of the following side effects gets serious or lasts longer than a few days:

Not known (frequency cannot be estimated from the available data)

- Sudden involuntary jerks, twitches of the muscles or muscle contractions (myoclonus)
- **Episodes of light headedness, feeling confused, abnormal movements, fainting and seizures (encephalopathy)**

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Heimlich Veronika 22.10.2026	