06.2021

Vimpat 10 Mg/Ml Solution For Infusion **וימפט 10 מ"ג/מ"ל תמיסה להזלפה**

Active ingredient: חומר פעיל:
LACOSAMIDE **לקוסמיד**

רופא/ה, רוקח/ת נכבד/ה,

- **אנו מתכבדים להודיעך כי אושר שינוי במשטר המינון של התכשיר.**
- עלון לרופא עודכן בהתאם ביוני 2021.
- העדכון מובא בהודעה זו, טקסט שנוסף לעלון מופיע על רקע צהוב, טקסט שהוסר מסומן בקו חוצה.

להלן נוסח ההתוויה המאושר לתכשיר:

Vimpat is indicated as monotherapy and adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adults, adolescents and children from 4 years of age with epilepsy.

העדכון בעלון לרופא נעשה בסעיפים הבאים:

4.2 P

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Initiation of lacosamide treatment with a loading dose

Lacosamide treatment may also be initiated with a single loading dose of 200 mg, followed approximately 12 hours later by a 100 mg twice a day (200 mg/day) maintenance dose regimen. Subsequent dose adjustments should be performed according to individual response and tolerability as described above. A loading dose may be initiated in patients in situations when the physician determines that rapid attainment of lacosamide steady state plasma concentration and therapeutic effect is warranted. It should be administered under medical supervision with consideration of the potential for increased incidence of serious cardiac arrhythmia and central nervous system adverse reactions (see section 4.8). Administration of a loading dose has not been studied in acute conditions such as status epilepticus.

Discontinuation

In accordance with current clinical practice, if lacosamide has to be discontinued, it is recommended this be done gradually (e.g. taper the daily dose by 200 mg/week).

In patients who develop serious cardiac arrhythmia, clinical benefit/risk assessment should be performed and if needed lacosamide should be discontinued.

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4.4 Special warnings and precautions for use

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Cardiac rhythm and conduction

Dose-related prolongations in PR interval with lacosamide have been observed in clinical studies. Lacosamide should be used with caution in patients with underlying proarrhythmic conditions such as patients with known cardiac conduction problems or severe cardiac disease (e.g. myocardial ischaemia/infarction, heart failure, structural heart disease or cardiac sodium channelopathies) or patients treated with medicinal products affecting cardiac conduction, including antiarrhythmics and sodium channel blocking antiepileptic medicinal products (see section 4.5), as well as ~~known conduction problems, severe cardiac disease (e.g. history of myocardial infarction or heart failure)~~ in elderly patients.

In these patients it should be considered to perform an ECG before a lacosamide dose increase above 400 mg/day and after lacosamide is titrated to steady-state.

~~Second-degree or higher AV block has been reported in post-marketing experience.~~ In the placebo-controlled trials of lacosamide in epilepsy patients, atrial fibrillation or flutter were not reported; however, both have been reported in open-label epilepsy trials and in post-marketing experience ~~(see section 4.8)~~.

In post-marketing experience, AV block (including second degree or higher AV block) has been reported. In patients with proarrhythmic conditions, ventricular tachyarrhythmia has been reported. In rare cases, these events have led to asystole, cardiac arrest and death in patients with underlying proarrhythmic conditions.

Patients should be made aware of the symptoms of cardiac arrhythmia ~~second-degree or higher AV block~~ (e.g. slow, rapid or irregular pulse, palpitations, shortness of breath, feeling ~~of~~ lightheaded, ~~and~~ fainting) ~~and of the symptoms of atrial fibrillation and flutter (e.g. palpitations, rapid or irregular pulse, shortness of breath)~~. Patients should be counselled to seek immediate medical advice ~~should any of~~ if these symptoms occur.
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4.5 Interaction with other medicinal products and other forms of interaction

Lacosamide should be used with caution in patients treated with medicinal products known to be associated with PR prolongation (including sodium channel blocking antiepileptic medicinal products ~~e.g. carbamazepine, lamotrigine, eslicarbazepine, pregabalin~~) and in patients treated with ~~class I~~ antiarrhythmics. However, subgroup analysis in clinical trials did not identify an increased magnitude of PR prolongation in patients with concomitant administration of carbamazepine or lamotrigine ~~in clinical trials~~.
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4.8 Undesirable effects

(…)

System organ class	Very common	Common	Uncommon	Not known
(…)				
Nervous system disorders	Dizziness Headache	Balance disorder ~~Coordination abnormal~~ Memory impairment Cognitive disorder Somnolence Tremor Nystagmus Hypoesthesia Dysarthria Disturbance in attention Paraesthesia	Syncope[2] Coordination abnormal	Convulsion[3]
(…)				
Cardiac disorders			Atrioventricular block[1,2] Bradycardia[1,2] Atrial Fibrillation [1,2] Atrial Flutter[1,2]	Ventricular tachyarrhythmia[1]
(…)				

(…)

Laboratory abnormalities

Abnormalities in liver function tests have been observed in placebo-controlled trials with lacosamide in adult patients with partial-onset seizures who were taking 1 to 3 concomitant antiepileptic medicinal products. Elevations of ALT to ≥ 3x ULN occurred in 0.7 % (7/935) of Vimpat patients and 0 % (0/356) of placebo patients.

- העלון לרופא נשלחו למשרד הבריאות לצורך העלאתו למאגר התרופות שבאתר משרד הבריאות.
- ניתן לקבל עלון זה מודפס על ידי פניה ישירה לבעל הרישום:
ניאופרם בע"מ, רח' השילוח 6, ת.ד. 7063, פתח תקווה 4917001, טלפון: 03-9373737.

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