12/2019

רופא/ה, רוקח/ת נכבד/ה,

ניאופרם שמחה לבשר על אישור שינוי גיל המטופלים ועדכון עלוני התכשיר:

## בריביאקט 10 מ"ג/מ"ל תמיסה להזרקה/הזלפה

## Briviact 10 mg/ml solution for injection/infusion

החומר הפעיל וכמותו:

בריביאקט 10 מ"ג/מ"ל תמיסה להזרקה/הזלפה מכיל 10 מ"ג בריבאראצטאם (brivaracetam 10 mg) בכל מ"ל תמיסה.

התכשיר אושר לטיפול בילדים החל מגיל 4 שנים ומעלה, להתוויה הבאה:

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

**בהתאם לעדכון גיל המטופלים המאושר לשימוש בתכשיר, עודכן מידע בטיחותי בעלון לצרכן במתכונת עלון לרופא כדלקמן:**

**עדכונים בפרקים השונים בעלון לצרכן מודגשים להלן בצהוב:**

סעיף 4.2 Posology and method of administration

*Renal impairment*

No dose adjustment is needed in patients with impaired renal function (see section 5.2). Brivaracetam is not recommended in end-stage renal disease patients undergoing dialysis due to lack of data.
Based on data in adults, no dose adjustment is necessary in paediatric patients with impaired renal function.

*Hepatic impairment*

Exposure to brivaracetam was increased in adult patients with chronic liver disease. in addition, a 50 mg/day starting dose should be considered. In children and adolescents weighing 50 kg or greater, a 50 mg/day starting dose is recommended. A maximum daily dose of 150 mg administered in 2 divided doses is recommended for all stages of hepatic impairment (see sections 4.4 and 5.2).In children and adolescents weighing less than 50 kg, a 1 mg/kg/day starting dose is recommended. The maximum dose should not exceed 3 mg/kg/day. No clinical data are available in paediatric patients with hepatic impairment.

*Paediatric population*

The physician should prescribe the most appropriate formulation and strength according to weight and dose. It is recommended to parent and care giver to administer Briviact oral solution with the measuring device (10 ml or 5 ml oral dosing syringe) provided in the carton box.

The following table summarises the recommended posology for children from 4 years of age and adolescents. More details are provided below the table.

| | Children (≥4 years) and adolescents ≥50 kg<br><br>Administered in 2 equally divided doses | Children (≥4 years) and adolescents <50 kg<br><br>Administered in 2 equally divided doses |
|---|---|---|
| Therapeutic dose range | 50 - 200 mg/day | 1 - 4 mg/kg/day |
| Recommended starting dose | 50 mg/day<br>(or 100 mg/day)* | 1 mg/kg/day<br>(or 2 mg/kg/day)* |
| Recommended maintenance dose | 100 mg/day | 2 mg/kg/day |

* Based on physician assessment of need for seizure control.

*Children (from 4 years of age) and adolescents weighing 50 kg or more*

The recommended starting dose is 50mg/day. Brivaracetam may also be initiated at 100 mg/day based on physician assessment of need for seizure control. The dose should be administered in two equally divided doses, once in the morning and once in the evening.The recommended maintenance dose is 100 mg/day. Based on individual patient response, the dose may be adjusted in the effective dose range of 50 mg/day and 200 mg/day.

*Children (from 4 years of age) and adolescents weighing less than 50 kg*

The recommended starting dose is 1mg/kg/day. Brivaracetam may also be initiated at 2 mg/kg/day based on physician assessment of need for seizure control. The dose should be administered in two equally divided doses, once in the morning and once in the evening. The recommended maintenance dose is 2 mg/kg/day. Based on individual patient response, the dose may be adjusted in the effective dose range of 1 mg/kg/day and 4 mg/kg/day.

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העלון לרופא ולצרכן מכילים עדכוני נוסח נוספים שאינם מהווים עדכון מידע בטיחותי.

העלון לרופא והעלון לצרכן נשלחו למשרד הבריאות לצורך העלאתם למאגר התרופות שבאתר משרד הבריאות.

ניתן לקבל עלונים אלה מודפסים על ידי פניה ישירה לבעל הרישום:

ניאופרם בע"מ, השילוח 6, ת.ד. 7063, פתח תקווה 4917001. טלפון: 03-9373737, פקס: 03-9373770

בברכה,

כיאן בסול
רוקחת ממונה, בעל רישום ניאופרם בע"מ