

נובמבר 2021

Vimpat 10 Mg/MI Solution For Infusion

וימפט 10 מ"ג/מ"ל תמיסה להזלפה

Active ingredient:
LACOSAMIDE

חומר פעיל:
לקוסמיד

רופא/ה, רוקח/ת נכבד/ה,

- ניאופרם בע"מ מתכבדת להודיעך אודות עדכונים בעלון לרופא של התכשיר בנדון.
- העדכון מובא בהודעה זו, טקסט שנוסף לעלון מופיע על רקע צהוב, טקסט שהוסר מסומן בקו חוצה על רקע כחול.

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 Posology and method of administration

Monotherapy doses **to be taken twice daily** for children from 4 years of age **weighing less than 40 kg⁽⁺⁾**:

Weight	0.1 ml/kg (1 mg/kg) Starting dose	0.2 ml/kg (2 mg/kg)	0.3 ml/kg (3 mg/kg)	0.4 ml/kg (4 mg/kg)	0.5 ml/kg (5 mg/kg)	0.6 ml/kg (6 mg/kg) Maximum recommended dose
10 kg	1 ml (10 mg)	2 ml (20 mg)	3 ml (30 mg)	4 ml (40 mg)	5 ml (50 mg)	6 ml (60 mg)
15 kg	1.5 ml (15 mg)	3 ml (30 mg)	4.5 ml (45 mg)	6 ml (60 mg)	7.5 ml (75 mg)	9 ml (90 mg)
20 kg	2 ml (20 mg)	4 ml (40 mg)	6 ml (60 mg)	8 ml (80 mg)	10 ml (100 mg)	12 ml (120 mg)
25 kg	2.5 ml (25 mg)	5 ml (50 mg)	7.5 ml (75 mg)	10 ml (100 mg)	12.5 ml (125 mg)	15 ml (150 mg)
30 kg	3 ml (30 mg)	6 ml (60 mg)	9 ml (90 mg)	12 ml (120 mg)	15 ml (150 mg)	18 ml (180 mg)
35 kg	3.5 ml (35 mg)	7 ml (70 mg)	10.5 ml (105 mg)	14 ml (140 mg)	17.5 ml (175 mg)	21 ml (210 mg)

⁽⁺⁾ Children and adolescents less than 50 kg should preferably start the treatment with Vimpat 10 mg/ml syrup. Vimpat 10 mg/ml solution for infusion is an alternative for patients when oral administration is temporarily not feasible.

Monotherapy doses **to be taken twice daily** for children and adolescents from 4 years of age **weighing 40 kg to under 50 kg⁽¹⁾⁽²⁾**:

Weight	0.1 ml/kg (1 mg/kg) Starting dose	0.2 ml/kg (2 mg/kg)	0.3 ml/kg (3 mg/kg)	0.4 ml/kg (4 mg/kg)	0.5 ml/kg (5 mg/kg) Maximum recommended dose
40 kg	4 ml (40 mg)	8 ml (80 mg)	12 ml (120 mg)	16 ml (160 mg)	20 ml (200 mg)

45 kg	4.5 ml (45 mg)	9 ml (90 mg)	13.5 ml (135 mg)	18 ml (180 mg)	22.5 ml (225 mg)
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⁽⁺⁾ Children and adolescents less than 50 kg should preferably start the treatment with Vimpat 10 mg/ml syrup. Vimpat 10 mg/ml solution for infusion is an alternative for patients when oral administration is temporarily not feasible.

⁽²¹⁾ Dosage in adolescents 50 kg or more is the same as in adults.

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Adjunctive therapy doses **to be taken twice daily** for children from 4 years of age **weighing less than 20 kg⁽⁺⁾**:

Weight	0.1 ml/kg (1 mg/kg) Starting dose	0.2 ml/kg (2 mg/kg)	0.3 ml/kg (3 mg/kg)	0.4 ml/kg (4 mg/kg)	0.5 ml/kg (5 mg/kg)	0.6 ml/kg (6 mg/kg) Maximum recommended dose
10 kg	1 ml (10 mg)	2 ml (20 mg)	3 ml (30 mg)	4 ml (40 mg)	5 ml (50 mg)	6 ml (60 mg)
15 kg	1.5 ml (15 mg)	3 ml (30 mg)	4.5 ml (45 mg)	6 ml (60 mg)	7.5 ml (75 mg)	9 ml (90 mg)

⁽⁺⁾ Children and adolescents less than 50 kg should preferably start the treatment with Vimpat 10 mg/ml syrup. Vimpat 10 mg/ml solution for infusion is an alternative for patients when oral administration is temporarily not feasible.

Adjunctive therapy doses **to be taken twice daily** for children and adolescents from 4 years of age **weighing 20 kg to under 30 kg⁽⁺⁾**:

Weight	0.1 ml/kg (1 mg/kg) Starting dose	0.2 ml/kg (2 mg/kg)	0.3 ml/kg (3 mg/kg)	0.4 ml/kg (4 mg/kg)	0.5 ml/kg (5 mg/kg) Maximum recommended dose
20 kg	2 ml (20 mg)	4 ml (40 mg)	6 ml (60 mg)	8 ml (80 mg)	10 ml (100 mg)
25 kg	2.5 ml (25 mg)	5 ml (50 mg)	7.5 ml (75 mg)	10 ml (100 mg)	12.5 ml (125 mg)

⁽⁺⁾ Children and adolescents less than 50 kg should preferably start the treatment with Vimpat 10 mg/ml syrup. Vimpat 10 mg/ml solution for infusion is an alternative for patients when oral administration is temporarily not feasible.

Adjunctive therapy doses **to be taken twice daily** for children and adolescents from 4 years of age **weighing 30 kg to under 50 kg⁽⁺⁾**:

Weight	0.1 ml/kg (1 mg/kg) Starting dose	0.2 ml/kg (2 mg/kg)	0.3 ml/kg (3 mg/kg)	0.4 ml/kg (4 mg/kg) Maximum recommended dose
30 kg	3 ml (30 mg)	6 ml (60 mg)	9 ml (90 mg)	12 ml (120 mg)
35 kg	3.5 ml (35 mg)	7 ml (70 mg)	10.5 ml (105 mg)	14 ml (140 mg)
40 kg	4 ml (40 mg)	8 ml (80 mg)	12 ml (120 mg)	16 ml (160 mg)
45 kg	4.5 ml (45 mg)	9 ml (90 mg)	13.5 ml (135 mg)	18 ml (180 mg)

⁽⁺⁾ Children and adolescents less than 50 kg should preferably start the treatment with Vimpat 10 mg/ml syrup. Vimpat 10 mg/ml solution for infusion is an alternative for patients when oral administration is temporarily not feasible.

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4.8 Undesirable effects

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Tabulated list of adverse reactions

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System organ class	Very common	Common	Uncommon	Not Known
Nervous system disorders	Dizziness Headache	Balance disorder Memory impairment Cognitive disorder Somnolence Tremor Nystagmus Hypoesthesia Dysarthria Disturbance in attention Paraesthesia	Syncope ⁽²⁾ Coordination abnormal Dyskinesia	Convulsion ⁽³⁾

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- העלון לרופא נשלח 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.

בברכה,

אבי ילצינדג

רוקח ממונה

בעל הרישום: ניאופרם בע"מ