דצמבר 2023

הודעה על עדכון העלון לרופא:

Veklury® 100 mg Powder for Concentrate for Solution for Infusion (remdesivir 100 mg/vial)

רופאים ורוקחים נכבדים,

חברת גיליאד סיאנסז ישראל בע"מ מבקשת להודיעכם כי חל עדכון בעלון לרופא של התכשיר בנדון.

נוסח ההתוויה המאושרת :

Veklury is indicated for the treatment of coronavirus disease 2019 (COVID-19) in:

- adults and paediatric patients (at least 4 weeks of age and weighing at least 3 kg) with pneumonia requiring supplemental oxygen (low- or high-flow oxygen or other non-invasive ventilation at start of treatment)
- adults who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19

השינויים מסומנים בעמוד הבא כאשר הטקסט המודגש באדום הוסף לעלון ואילו הטקסט המחוק ~~בקו חוצה~~ נגרע ממנו.

במכתב זה מופיעים העדכונים המשמעותיים ביותר.

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות:

https://data.health.gov.il/drugs/index.html#/byDrug

כמו כן ,ניתן לקבלו מודפס על ידי פנייה לבעל הרישום:

גיליאד סיאנסז ישראל בע"מ, רחוב החרש 4 ,ת.ד. 6090, פארק העסקים הוד השרון 4524075, ישראל .

בברכה,

הדר אוליאר

רוקחת ממונה

גיליאד סיאנסז ישראל בע"מ

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4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Veklury is indicated for the treatment of coronavirus disease 2019 (COVID-19) in:

- adults and ~~in adolescents (aged 12 to less than 18 years~~ paediatric patients (at least 4 weeks of age and weighing at least ~~40~~ 3 kg) with pneumonia requiring supplemental oxygen (low- or high-flow oxygen or other non-invasive ventilation at start of treatment)
- adults who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19

(see section 5.1)

4.2 Posology and method of administration

~~Use of remdesivir is confined to healthcare facilities in which patients can~~ Patients should be monitored ~~closely~~ when receiving remdesivir (see section 4.4).

Patients receiving remdesivir in an outpatient setting should be monitored according to local medical practice. Use under conditions where treatment of severe hypersensitivity reactions, including anaphylaxis, is possible.

Posology

[…]

Table 1: Recommended dose in adults and paediatric patients

	Given by intravenous infusion		
	Adults	**Paediatric patients (weighing at least 40 kg)**	**Paediatric patients at least 4 weeks old (weighing at least 3 kg but less than 40 kg)**
Day 1 (single loading dose)	200 mg	200 mg	5 mg/kg
Day 2 and onwards (once daily)	100 mg	100 mg	2.5 mg/kg

Table 2: Treatment duration

	Adults	**Paediatric patients (weighing at least 40 kg)**	**Paediatric patients at least 4 weeks old (weighing at least 3 kg but less than 40 kg)**
Patients with **pneumonia and requiring supplemental oxygen**	The recommended duration of treatment is 5 days	The recommended duration of treatment is 5 days	Daily for up to a total of 10 days
Patients who **do not require supplemental oxygen and are at increased risk for progressing to severe COVID-19**	The total duration of treatment should be 3 days, starting as soon as possible after diagnosis of COVID-19 and within 7 days of the onset of symptoms.	Not applicable.	Not applicable.

Special populations

[…]

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Paediatric population
~~Remdesivir is not indicated for children under the age of 12 years and weighing < 40 kg~~
The safety and efficacy of remdesivir in children ~~under the~~ less than 4 weeks of age ~~of 12 years~~ and weighing ~~< 40~~ less than 3 kg have not yet been established. No data are available.

Immunocompromised population
The safety and efficacy of remdesivir in immunocompromised patients have not yet been established. Only limited data are available (see section 4.4).

Method of administration

[…]

Table ~~1~~3: Recommended rate of infusion – for reconstituted and diluted remdesivir powder for concentrate for solution for infusion in adults and paediatric patients weighing at least 40 kg

Infusion Bag Volume	Infusion Time	Rate of Infusion
250 mL	30 min	8.33 mL/min
	60 min	4.17 mL/min
	120 min	2.08 mL/min
100 mL	30 min	3.33 mL/min
	60 min	1.67 mL/min
	120 min	0.83 mL/min

Table 4: Recommended rate of infusion – for reconstituted and diluted remdesivir powder for concentrate for solution for infusion in paediatric patients at least 4 weeks of age and weighing at least 3 kg but less than 40 kg

Infusion Bag Volume	Infusion Time	Rate of Infusion[a]
100 mL	30 min	3.33 mL/min
	60 min	1.67 mL/min
	120 min	0.83 mL/min
50 mL	30 min	1.67 mL/min
	60 min	0.83 mL/min
	120 min	0.42 mL/min
25 mL	30 min	0.83 mL/min
	60 min	0.42 mL/min
	120 min	0.21 mL/min

a Rate of infusion may be adjusted based on total volume to be infused.

4.4 Special warnings and precautions for use

Hypersensitivity including infusion-related and anaphylactic reactions

[…]
Monitor patients for hypersensitivity reactions during and following administration of remdesivir as clinically appropriate. Patients receiving remdesivir in an outpatient setting should be monitored after administration according to local medical practice.

[…]

Immunocompromised patients:

It is unclear if the treatment duration of three days is sufficient to clear the virus in immunocompromised patients, in whom prolonged viral shedding occurs. There is a potential risk of resistance development. Only limited data are available.

[…]

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4.8 Undesirable effects

Prothrombin time prolonged

[…]

In Study GS-US-540-9012, the incidence of increased prothrombin time or INR was similar in patients treated with remdesivir compared to placebo.

Paediatric population

The safety assessment of remdesivir in children 4 weeks of age and older and weighing at least 3 kg with COVID-19 is based on data from a Phase 2/3, open-label clinical trial (Study GS-US-540-5823) that enrolled 53 patients who were treated with remdesivir (see Section 5.1). The adverse reactions observed were consistent with those observed in clinical trials of remdesivir in adults.

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