מרץ 2024

הודעה על עדכון עלונים:

EPCLUSA® film coated tablets

(SOFOSBUVIR 400 MG / VELPATASVIR 100 MG)

רופאים ורוקחים נכבדים,

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

נוסח ההתוויה המאושרת:

Epclusa is indicated for the treatment of chronic hepatitis C virus (HCV) infection in patients aged 12 years and older or weighing at least 30 kg.

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

במכתב זה מופיעים העדכונים המשמעותיים ביותר.

העלונים נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות:

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

כמו כן ,ניתן לקבלם מודפסים על ידי פנייה לבעל הרישום:

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

בברכה,

ילנה קפלן

רוקחת ממונה

גיליאד סיאנסז ישראל בע"מ

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4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Epclusa is indicated for the treatment of chronic hepatitis C virus (HCV) infection in patients aged 12 years and older or weighing at least 30 kg ~~adults~~ (see sections 4.2, 4.4 and 5.1)

4.2 Posology and method of administration

Epclusa treatment should be initiated and monitored by a physician experienced in the management of patients with HCV infection.

Posology

The recommended dose of Epclusa in adults is one 400 mg/100 mg tablet, taken orally, once daily with or without food (see section 5.2).

The recommended dose of Epclusa in patients aged 12 to < 18 years or weighing at least 30 kg is one 400 mg/100 mg tablet, taken orally, once daily with or without food (see section 5.2).

Table 1: Recommended treatment and duration for adults regardless of ~~all~~ HCV genotype~~s~~

Adult patient population[a]	Treatment and duration
Patients without cirrhosis and patients with compensated cirrhosis	Epclusa for 12 weeks Addition of ribavirin may be considered for genotype 3 infected patients with compensated cirrhosis (see section 5.1.)
Patients with decompensated cirrhosis	Epclusa + ribavirin for 12 weeks

a Includes patients co-infected with human immunodeficiency virus (HIV) and patients with recurrent HCV post-liver transplant (see section 4.4.).

When used in combination with ribavirin, refer also to the Prescribing Information of the medicinal product containing ribavirin.

The following dosing is recommended for adults where ribavirin is divided in two daily doses and given with food:

Table 2: Guidance for ribavirin dosing when administered with Epclusa to ~~patients~~ adults with decompensated cirrhosis

Adult patient	Ribavirin dose
Child-Pugh-Turcotte (CPT) Class B cirrhosis pre-transplant	1,000 mg per day for patients < 75 kg and 1,200 mg for those weighing ≥ 75 kg
CPT Class C cirrhosis pre-transplant CPT Class B or C post-transplant	Starting dose of 600 mg, which can be titrated up to a maximum of 1,000/1,200 mg (1,000 mg for patients weighing < 75 kg and 1,200 mg for patients weighing ≥ 75 kg) if well tolerated. If the starting dose is not well tolerated, the dose should be reduced as clinically indicated based on haemoglobin levels

If ribavirin is used in genotype 3 infected adult patients with compensated cirrhosis (pre- or post-transplant) the recommended dose of ribavirin is 1,000/1,200 mg (1,000 mg for adult patients weighing < 75 kg and 1,200 mg for adult patients weighing ≥ 75 kg).

For ribavirin dose modifications, refer to the Prescribing Information of the medicinal product containing ribavirin.

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Patients should be instructed that if vomiting occurs within 3 hours of dosing an additional tablet of Epclusa should be taken. If vomiting occurs more than 3 hours after dosing, no further dose of Epclusa is needed (see section 5.1).

If a dose of Epclusa is missed and it is within 18 hours of the normal time, patients should be instructed to take the tablet as soon as possible and then patients should take the next dose at the usual time. If it is after 18 hours then patients should be instructed to wait and take the next dose of Epclusa at the usual time. Patients should be instructed not to take a double dose of Epclusa.

Adult patients who have previously failed therapy with an NS5A-containing regimen
Epclusa + ribavirin for 24 weeks may be considered (see section 4.4).

Elderly
No dose adjustment is warranted for elderly patients (see section 5.2).

Renal impairment
No dose adjustment of Epclusa is required for patients with mild or moderate renal impairment.

Safety data are limited in patients with severe renal impairment (estimated glomerular filtration rate [eGFR] < 30 mL/min/1.73 m2) and end stage renal disease (ESRD) requiring haemodialysis. Epclusa can be used in these patients with no dose adjustment when no other relevant treatment options are available (see sections 4.4, 4.8, 5.1 and 5.2).

Epclusa has not been studied in patients with severe renal impairment not requiring dialysis.

Hepatic impairment
No dose adjustment of Epclusa is required for patients with mild, moderate, or severe hepatic impairment (CPT Class A, B, or C) (see section 5.2). Safety and efficacy of Epclusa have been assessed in patients with CPT Class B cirrhosis, but not in patients with CPT Class C cirrhosis (see sections 4.4 and 5.1).

Paediatric population
The safety and efficacy of Epclusa in children ~~and adolescents~~ aged less than ~~18~~ 12 years and weighing less than 30 kg have not yet been established. ~~No data are available.~~

Method of administration
For oral use.

Patients should be instructed to swallow the tablet whole with or without food (see section 5.2). Due to the bitter taste, it is recommended that the film-coated tablet is not chewed or crushed.

4.8 Undesirable effects
[…]
Paediatric population

The safety assessment of Epclusa in paediatric patients aged 12 years and older is based on data from a Phase 2, open-label clinical study (Study 1143) that enrolled 102 patients who were treated with sofosbuvir/velpatasvir for 12 weeks. The adverse reactions observed were consistent with those observed in clinical studies of Epclusa in adults.
[…]

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העדכונים המהותיים שבוצעו בעלון לצרכן:

אם אפקלוזה נרשמה לילדך, אנא שים לב כי כל המידע בעלון זה מיועד לילדך (במקרה זה קרא "ילדך" במקום "הנך".

1. למה מיועדת אפקלוזה?

אפקלוזה ניתנת לטיפול בזיהום נגיפי כרוני (ארוך טווח) של הכבד שנקרא הפטיטיס **C**, ~~במבוגרים~~ במטופלים בני ~~18~~ 12 שנים ומעלה או השוקלים לפחות 30 ק"ג.

2. לפני השימוש באפקלוזה

[...]

ילדים ומתבגרים
אין לתת תרופה זו לילדים ~~ולמתבגרים~~ בני פחות מ-~~18~~ 12 שנים והשוקלים פחות מ-30 ק"ג.
השימוש באפקלוזה בילדים ובמטופלים מתחת לגיל 12 שנים ~~מתבגרים~~ טרם ~~נחקר~~ הוכח.

[...]

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