GILEAD | Medical Information

Epclusa® (sofosbuvir/velpatasvir) Use in Pregnancy

This document is in response to your request for information regarding the use of Epclusa® (sofosbuvir/velpatasvir [SOF/VEL]) for the treatment of HCV in women who are pregnant.

Some data may be outside of the US FDA-approved prescribing information. In providing this data, Gilead Sciences, Inc. is not making any recommendation on its clinical relevance or use of any Gilead product(s). For information about the approved conditions of use of any Gilead drug product, please consult the FDA-approved prescribing information.

The full indication, important safety information, and boxed warnings are available at: www.gilead.com/-/media/files/pdfs/medicines/liver-disease/epclusa/epclusa_pi.

Summary

Product Labeling[1]

No adequate human data are available to establish whether SOF/VEL poses a risk to pregnancy outcomes.

Clinical Data on the Use of SOF/VEL in Pregnancy

A cumulative review of safety data from 335 SOF/VEL pregnancy cases (337 pregnancy outcomes; 2 twin pregnancies) found 123 pregnancies with reported outcomes. Among these, 74 resulted in live births, with congenital abnormalities reported in 12.1% of live births; none were assessed as causally related to SOF/VEL after further review. No cases of vertical transmission were reported. Data on treatment completion and SVR were limited as only 20 females completed treatment during pregnancy, and SVR was confirmed in 8 cases. Timing of SOF/VEL initiation was frequently missing, with 53% of cases lacking exposure timing data.[2]

The ongoing, phase 4, open-label, single-arm STORC study is assessing safety and efficacy outcomes of chronic HCV treatment with SOF/VEL once daily for 12 weeks during pregnancy. Interim data showed a 96% maternal SVR rate among the 54 participants who completed SVR assessment, as well as no perinatal transmission with SOF/VEL. No SAEs were related to SOF/VEL. Two participants discontinued SOF/VEL.[3]

In a study conducted to assess whether a test-and-treat model with SOF-based regimens for pregnant women (N=14) who were actively using drugs improved HCV treatment starts and SVR rates, the overall SVR rate among pregnant women evaluated in the third trimester was 100%. All participants self-reported complete adherence, and no cases of vertical transmission were reported.[4]

In a phase 1, open-label PK study evaluating SOF/VEL in 10 pregnant women, VEL exposures and SOF C_{max} were similar between the pregnant participants and the non-pregnant reference cohort. The SVR12 rate was 100% (n=8 with SVR visit), and none of the 8 infants with HCV RNA follow-up data had detectable values during the 12 months of follow-up. Maternal AEs included headache, nausea, vomiting, heartburn, and fatigue.

One Grade 3 AE of vomiting resulted in treatment discontinuation. Among the infants, there were 2 preterm births (<37 weeks of gestation) and 3 NICU admissions.[5]

Product Labeling[1]

Warnings and Precautions

Risks associated with RBV and SOF/VEL combination treatment

If SOF/VEL is administered with RBV, the warnings and precautions for RBV apply to this combination regimen. Refer to the RBV prescribing information for a full list of the warnings and precautions for RBV.

Use in Specific Populations

Pregnancy

Risk summary

If SOF/VEL is administered with RBV, the combination regimen is contraindicated in pregnant women and in men whose female partners are pregnant. Refer to the RBV prescribing information for more information on RBV-associated risks of use during pregnancy.

No adequate human data are available to establish whether SOF/VEL poses a risk to pregnancy outcomes. In animal reproduction studies, no evidence of adverse developmental outcomes was observed with the components of SOF/VEL at exposures greater than those in humans at the RHD. During organogenesis in the mouse, rat, and rabbit, systemic exposures (AUC) to VEL were approximately 31 (mice), 6 (rats), and 0.4 (rabbits) times the exposure in humans at the RHD, while exposures to the predominant circulating metabolite of SOF (GS-331007) were approximately 4 (rats) and 10 (rabbits) times the exposure in humans at the RHD. In rat pre/postnatal development studies, maternal systemic exposures (AUC) of VEL and GS-331007 were approximately 5 times the exposures of each component in humans at the RHD.

The background risk of major birth defects and miscarriage for the indicated population is unknown. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

Data

SOF: SOF was administered orally to pregnant rats (up to 500 mg/kg/day) and rabbits (up to 300 mg/kg/day) on gestation Days 6 to 18 and 6 to 19, respectively, and also to rats (oral doses up to 500 mg/kg/day) on gestation Day 6 to lactation/post-partum Day 20.
No significant effects on embryo-fetal (rats and rabbits) or pre/postnatal (rats) development were observed at the highest doses tested. The systemic exposures (AUC) of the predominant circulating metabolite of SOF (GS-331007) during gestation were approximately 4 (rats) and 10 (rabbits) times the exposure in humans at the RHD.

VEL: VEL was administered orally to pregnant mice (up to 1000 mg/kg/day), rats (up to 200 mg/kg/day) and rabbits (up to 300 mg/kg/day) on gestation Days 6 to 15, 6 to 17, and 7 to 20, respectively, and also to rats (oral doses up to 200 mg/kg) on gestation Day 6 to

lactation/post-partum Day 20. No significant effects on embryo-fetal (mice, rats, and rabbits) or pre/postnatal (rats) development were observed at the highest doses tested. The systemic exposures (AUC) of VEL during gestation were approximately 31 (mice), 6 (rats), and 0.4 (rabbits) times the exposure in humans at the RHD.

Females and males of reproductive potential

If SOF/VEL is administered with RBV, the information for RBV with regards to pregnancy testing, contraception, and infertility also applies to this combination regimen. Refer to RBV prescribing information for additional information.

Clinical Data on the Use of SOF/VEL in Pregnancy

Cumulative Review of Safety Data From Patients Treated With SOF/VEL During Pregnancy[2]

Study design and demographics

A cumulative review of the Gilead Pharmacovigilance Database evaluated safety data from reports of SOF/VEL use during pregnancy. Data from February 2016 to June 2024 were collected from spontaneous reports from HCPs and patients, clinical studies (including the STORC study summarized below), solicited nonclinical reports (eg, patient registries, post-marketing surveillance programs), clinical literature, and published case reports. Overall, there were 335 pregnancy cases (337 pregnancy outcomes; 2 twin pregnancies were reported), and most cases (n=216; 64.5%) were spontaneously reported; 66 (19.7%) were from clinical studies, 46 (13.7%) were from solicited reports, 6 (1.79%) were from clinical studies, and 1 (0.3%) was from spontaneous literature.

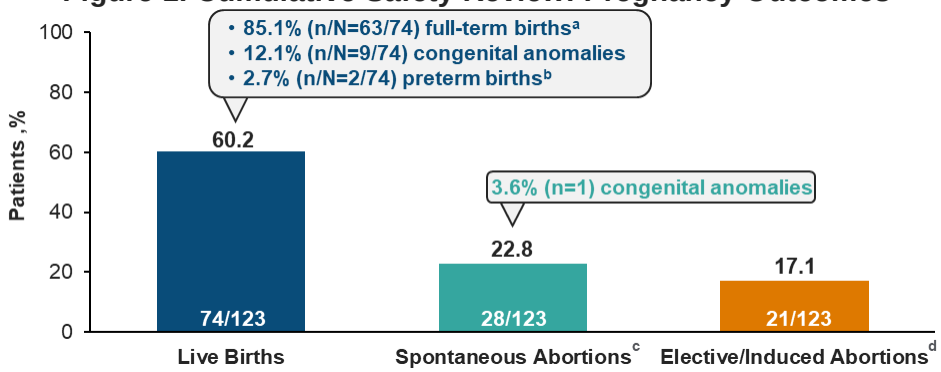
Most cases (n=188; 62%) were reported from the US; otherwise, countries with ≥5 reports were Canada (n=30; 8.9%), Australia (n=18; 5.3%), and the UK (n=17; 5.1%). Of the 153 cases that reported maternal age, the median (range) was 31 (17–52) years. Ethnicity data were reported in only 83 cases; most (n=58; 70%) identified as Caucasian.

Results

The timing of SOF/VEL exposure was unknown in 53.4% of cases (n=180); SOF/VEL was initiated during the first trimester in 42.1% (n=142), the second trimester in 3.3% (n=11), and the third trimester in 1.2% of cases (n=4). Among the 74 live births, the timing of SOF/VEL initiation was unknown in 48 cases; of the 26 cases with data, treatment was initiated during the first trimester in 16, the second trimester in 8, and the third trimester in 2 cases.

Pregnancy outcomes were documented in 123 of the 335 pregnancy cases (36.5%; Table 1), whereas 214 case outcomes (63.5%) were either unknown/not reported (n=195) or pending (n=19). Most pregnancies resulted in live births (n=74), and congenital abnormalities occurred in 12.1% of the live births (unrelated to SOF/VEL). None of the 28 spontaneous abortion cases were deemed to be causally related to SOF/VEL use (Figure 1).

Figure 1. Cumulative Safety Review: Pregnancy Outcomes[2]



[a]Caesarean delivery occurred in 16 live births (21.6%).
[b]Occurred at 30 and 33 weeks of gestation.
[c]Defined as a nonviable intrauterine pregnancy that occurred within 12 weeks and 6 days of gestation. Possible explanations were provided for 9 cases, as follows: preexisting history of abortion, ectopic pregnancy, polycystic ovaries, history of drug abuse (eg, alcohol, substance, and tobacco use), concomitant medications (eg, gabapentin, clonidine, methadone, fentanyl), and underlying health conditions (eg, hepatic failure, depression).
[d]Defined as an intentional interruption of pregnancy by medical or surgical intervention prior to 20 weeks of gestation.

Effectiveness outcomes were incomplete and not routinely documented. SVR was confirmed in 8 cases (2.4%). Treatment discontinuation data were available for 72 cases. SOF/VEL was discontinued in 52 cases (72.2%), and 32 discontinuations occurred in the first trimester; treatment was completed in 20 cases (27.8%), and 7 of those cases occurred in the first trimester. No cases of vertical transmission were reported.

Overall, 10 cases with congenital abnormalities (8.1%) were reported among the 123 cases with documented outcomes; of these, 9 were among the 74 live births and 1 occurred with a spontaneous abortion (Table 1). None were deemed to be causally related to SOF/VEL following medical review.

Table 1. Cumulative Safety Review: Congenital Abnormalities Among Live Births (n=9)[2]

Trimester of SOF/VEL Initiation	Data Source; Country	Congenital Abnormality
Unknown	Spontaneous report; Brazil	Kidney malformation
First	Study IN-CA-337-2100; Canada	Fallot's tetralogy, congenital ureteric anomaly, congenital hydronephrosis
First	Spontaneous report; US	Fetal growth restriction, limb asymmetry
Second	Study IN-US-342-5634; US	Talipes
Second	Study IN-US-342-5634; US	Cryptorchism
Second	STORC Study; US	Retrognathia
Third	STORC Study; US	Congenital megacolon
Third	STORC Study; US	Periauricular skin tag
Third	STORC Study; US	Pyloric stenosis

Open-Label STORC Study

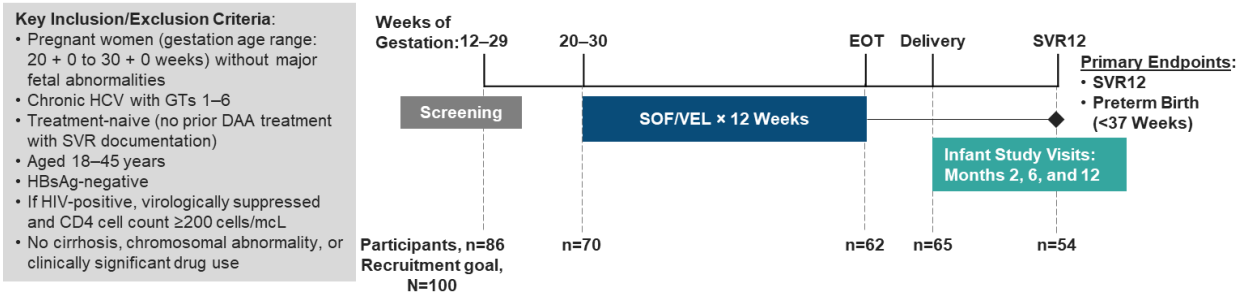
Study design and demographics

The ongoing, phase 4, open-label, single-arm STORC study is assessing safety and efficacy outcomes of chronic HCV treatment with SOF/VEL once daily for 12 weeks during pregnancy. Delivery outcomes, viral response, safety profile, and infant outcomes were

evaluated in the SOF/VEL-treated participants. The primary endpoints of this study were SVR12 and preterm birth (defined as <37 weeks; Figure 2).[3,6]

As of October 6, 2025, 70 participants were enrolled, and 54 participants completed bloodwork to assess for SVR; 7 were lost to follow-up, and 7 were either receiving treatment or awaiting their SVR assessment window. Baseline characteristics included a median (range) age of 32 (18–41) years. Injection or inhalant drug use was the most common mode of HCV acquisition (69% [n=48]), and 74% of participants (n=52) had a history of injection drug usage. Participant races included the following: White, 83% (n=58); multiracial, 7% (n=5); Asian, 3% (n=2); Native American, 3% (n=2); Black, 3% (n=2); Rohingya, 1% (n=1); and declined to answer, 1% (n=1). Hispanic/Latinx ethnicity was reported in 9% of participants (n=6). HCV GTs were as follows: GT 1, 59% (n=41); GT 2, 10% (n=7); and GT 3, 31% (n=22). Ninety-four percent of participants (n=66) had FIB-4 scores <1.45 and 6% (n=4) had FIB-4 scores >1.45 to <3.25. In previous pregnancies, 48 infants were exposed to HCV and 19 of those were tested for HCV; however, no previous perinatal transmission was reported. The median (range) gestational age at enrollment was 25 weeks + 4 days (20 + 3 to 30 + 0).[3]

Figure 2. STORC Study: Study Design[3,6,7]



Abbreviations: CD=clusters of differentiation; EOT=end of treatment; HBsAg=hepatitis B surface antigen.
Note: HCV VL and AEs were assessed during SOF/VEL treatment and through SVR12. For 12 months postdelivery in infants, HCV VL and AEs were assessed, and physical examinations and growth and neurodevelopment assessments were given.

Interim results

Interim data showed a 96% maternal SVR12 rate among the 54 participants who completed SVR assessment, and 2 treatment failures were noted (both had HCV GT 1a). No perinatal transmission occurred in the 50 infants with available data. Of the 66 deliveries, 8 (12.1%) were preterm, and the median (range) gestational age at delivery was 38 weeks + 1 day (33 + 5 to 42 + 0).[3] In an earlier report of data from 44 deliveries, 6 were preterm, including 2 with premature rupture of membranes at 36 + 4 weeks of gestation; 1 each with premature rupture of membranes and spontaneous preterm labor at 36 + 2 weeks of gestation; 1 with spontaneous preterm labor with breech presentation at 33 + 5 weeks of gestation; and 1 with spontaneous preterm labor with marginal placental abruption at 33 + 4 weeks of gestation.[7] There were no reports of cholestasis. Data from an observational cohort of pregnant participants who did not receive HCV treatment during pregnancy found higher rates of perinatal HCV transmission (8%; 26/314), preterm birth (16.1%; 40/249), and cholestasis in infants (6.8%; 17/249) than those observed in STORC.[3]

There were 319 AEs reported in mothers and 248 AEs reported in infants. Fifty-two AEs were deemed related to SOF/VEL, including the following: nausea/vomiting (n=20); gastroesophageal reflux disease (n=9); fatigue (n=8); headache (n=5); diarrhea (n=2); and arthralgias, elevated creatine kinase level, elevated AST level, insomnia, light sensitivity,

numbness in fingers, rash, and right kidney pain (each, n=1). There were 22 SAEs reported in mothers and 25 in infants; none were deemed related to SOF/VEL. Four congenital anomalies were reported: Hirschsprung disease, preauricular skin tag, pyloric stenosis, and retrognathia (each, n=1); none were related to SOF/VEL. Two participants discontinued SOF/VEL (nausea/vomiting, n=1; participant initiated [partner influence], n=1).[3]

HCV Treatment Initiation in the Third Trimester[4]

Study design

A study was conducted to assess whether a test-and-treat model with SOF-based regimens for treating pregnant women with HCV in their third trimester who were actively using drugs (defined as use within the past 6 months) improved HCV treatment starts and SVR rates (N=14). Participants were referred to a combination hepatology and addiction medicine clinic from addiction centers, syringe exchanges, high-risk obstetrics, Planned Parenthood, incarceration systems, and drug courts. Appointments with case managers and social workers were scheduled within 3 days, and additional services (eg, addiction therapy, medically assisted therapy, and HIV/PrEP management) were included. Test-and-treat approaches included same-day start, Medicare next-day rapid start, and next-day telemedicine start.

Results

The overall SVR rate among pregnant women who had available data was 100% (8/8). Eleven of the 14 participants received SOF/VEL, including 7 who began treatment on the same day test-and-treat approach. Of the 11 participants who received SOF/VEL, 6 achieved SVR, 2 were lost to follow-up, and 3 are pending SVR assessment. All participants self-reported complete adherence. No cases of vertical transmission were reported.

Open-Label PK Study

Study design, participant disposition, and demographics

A phase 1, open-label, single-center study evaluated the PK profile of 12 weeks of SOF/VEL in pregnant compared with non-pregnant women with chronic HCV infection. Delivery outcomes, viral response, and safety profile were also evaluated in the SOF/VEL-treated participants.[5,8] Study participants were HIV-negative and between 23 and 25 weeks of gestation at enrollment (Table 2). Eleven participants were enrolled in the study, and 10 participants were included in the primary PK analysis; 1 participant was excluded due to discontinuation of study treatment due to AEs (worsening of pregnancy-related hyperemesis) after 2 doses. Infants were followed for 12 months after delivery, and were assessed for HCV VL, AEs, physical examinations, growth, and neurodevelopment.[5]

The PK of SOF/VEL were evaluated at Weeks 3, 6, and 9 of treatment. Exposures to VEL, SOF, and the GS-331007 metabolite in plasma were compared with historical PK data in 25 non-pregnant women treated with SOF/VEL in registrational trials. Another analysis compared levels of 007-TP (the active form of SOF; collected before dosing during Weeks 3, 6, and 9 of treatment) in DBS and PBMCs from study participants with those collected from 58 non-pregnant participants who received LDV/SOF in another study; levels may be used as a surrogate of drug activation in various tissue types and a measure of adherence to SOF-based treatment.[5]

Table 2. Baseline Demographics and Disease Characteristics (Chappell et al)[5,9]

Key Demographics and Characteristics		Pregnant Participants (N=11)
Age, median (range), years		30 (25–39)[a]
Race, White/Black, n (%)		10 (91)/1 (9)[b]
HCV GT, 1/3, n (%)		8 (73)/3 (27)
Route of HCV acquisition (per self-report), n (%)	Injection drug use	6 (55)
	Razor or needle injury	2 (18)
	Other/unknown	2 (18)[c]/1 (9)
SCr, median (range), mg/dL		0.5 (0.4–0.6)
GFR, median (range), mL/min/1.73 m^2		126 (122–141)
Hct, median (range), %		36 (33–38)

[a]Among historical controls for plasma analysis (N=25), median (range) age was 51 (20–66) years and all were female. Among historical controls for DBS and PBMCs analysis (N=58), median (IQR) age was 51 (46–55) years, and 13 (22%) were female.
[b]Among historical controls for plasma analysis, 16 (64%) were White, 4 (16%) were Black, and 5 (20%) were Asian; among historical controls for DBS and PBMCs analysis, 43 (74%) were White, 12 (21%) were Black.
[c]Sex, n=1; tattoo, n=1.
Note: No patients had cirrhosis or HIV co-infection in the cohort of patients for plasma analysis. Among the historical control for DBS and PBMCs analysis, 15 (26%) had cirrhosis and 45 (78%) also had HIV.

PK results

VEL PK parameters and SOF C_{max} were similar between pregnant and non-pregnant participants; however, SOF AUC was 38% higher in the group of pregnant participants than in the non-pregnant reference group. The GS-331007 AUC and C_{max} were 38% and 43% lower, respectively, in the pregnant participant group than in the non-pregnant reference group (Table 3). Study authors attributed the differences observed between groups in SOF and GS-31007 exposures to slowed gastrointestinal motility and increased renal clearance during pregnancy.[5]

Table 3. PK Parameters in Pregnant Participants and Non-Pregnant Reference Group (Chappell et al)[5]

PK Parameters, GM (CV%)		Pregnant Participants (N=10)[a]	Non-Pregnant Participants (N=25)[b]	%GMR (90% CI)
SOF	AUC_T, h × ng/mL	2039.62 (29.75)	1483.83 (66.43)	1.38 (1.06–1.78)
	C_{max}, ng/mL	1455.09 (43.92)	1226.16 (59.46)	1.19 (0.88–1.6)
GS-331007	AUC_T, h × ng/mL	9588.94 (18.75)	15,361.31 (22.35)	0.62 (0.55–0.71)
	C_{max}, ng/mL	752.66 (21.85)	1312.17 (32.55)	0.57 (0.49–0.67)
VEL	AUC_T, h × ng/mL	3244.45 (39.89)	3570.65 (72.04)	0.91 (0.67–1.23)
	C_{max}, ng/mL	381.93 (38.35)	449.39 (77.12)	0.85 (0.63–1.15)
	C_T, ng/mL	40.56 (49)	49.77 (66.37)	0.82 (0.59–1.13)

Abbreviations: AUC_T=area under the concentration-time curve of the dosing interval; C_T=concentration at the end of the dosing interval; CV=coefficient of variation; GMR=geometric mean ratio.
[a]GM from 2 PK visits from individual participants' PK parameters were summarized.
[b]Historical intensive PK data from non-pregnant women from registrational trials who were administered SOF/VEL.

Levels of 007-TP in PBMCs were similar between or higher in pregnant study participants than non-pregnant participants treated with LDV/SOF; 007-TP levels in PBMCs were 2111 (1096–4066), 2808 (1559–5058), and 2212 (1267–3864) fmol/10^6 cells. DBS levels were approximately 50% lower among pregnant study participants than among non-pregnant participants. In DBS, GM (95% CI) levels of 007-TP at Weeks 3, 6, and 9 of treatment were 340 (287–403), 340 (278–418), and 356 (275–461) fmol/punch, respectively , which study investigators concluded may have been due to hemodilution.[8]

Efficacy[5]

All 10 participants in the PK analysis completed their study medication at the time of delivery, although 1 participant reported missing >1 dose per week during the last 3 weeks of treatment. Of the 8 participants who had SVR12 visits, all achieved SVR12. Two participants were lost to follow-up before the SVR12 visit, although 1 of these participants was later found to have an undetectable HCV VL.

Of the 10 infants enrolled at delivery, 9 were delivered at the study site, and none of these infants had detectable HCV RNA in cord blood at birth. Two of the 10 enrolled infants were lost to follow-up after delivery, and none of the remaining 8 infants had detectable HCV RNA during the 12 months of follow-up.

Safety[5]

There were 12 treatment-related maternal AEs in 9 participants, and most were Grade 1 (58%) or Grade 2 (33%) in severity: headache, n=4 (Grade 1, n=3; Grade 2, n=1); nausea/vomiting, n=3 (all were Grade 1); vomiting, n=2 (Grade 2, n=1; Grade 3, n=1); heartburn, n=2 (all were Grade 2); and fatigue, n=1 (Grade 1). One Grade 3 AE of vomiting resulted in treatment discontinuation. Three cases of postpartum hemorrhage (27%) and 2 cases of hypertensive disorder of pregnancy (18%) occurred. No instances of gestational diabetes or cholestasis were reported.

In infants, there were 2 preterm (<37 weeks of gestation) births due to maternal complications (preeclampsia and placenta previa) and 3 infants required NICU admission for respiratory distress (n=2) and neonatal opioid withdrawal syndrome (n=1). All infants weighed >2500 g at birth, and all maintained growth parameters within the normal ranges and trajectory during the follow-up period. Five SAEs occurred during the initial hospitalization: respiratory distress (n=2); hyperbilirubinemia, left clubbed foot, cryptorchidism, and positive urine toxicology test for cocaine which resulted in prolonged hospitalization (each, n=1). Fifty-eight AEs were reported during follow-up; none were deemed to be related to SOF/VEL. One infant underwent a referral for intervention due to motor development concerns; however, at the last follow-up, all infants had normal neurodevelopment assessments.

References

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Abbreviations

007-TP=active triphosphate form of SOF
AE=adverse event
AUC=area under the concentration-time curve
C_{max}=maximum measured concentration
DBS=dried blood spots
FIB-4=Fibrosis-4 index
GM=geometric mean
GS-331007=predominant circulating metabolite of SOF
GT=genotype
LDV=ledipasvir
NICU=neonatal intensive care unit
PBMC=peripheral blood mononuclear cell
PK=pharmacokinetic(s)
PrEP=pre-exposure prophylaxis
SAE=serious adverse event
SOF=sofosbuvir
STORC=SOF/VEL Treatment of Chronic Hepatitis C During Pregnancy
SVR=sustained virologic response
SVR12=sustained virologic response 12 weeks after end of treatment
VEL=velpatasvir
VL=viral load

Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Epclusa US Prescribing Information available at: www.gilead.com/-/media/files/pdfs/medicines/liver-disease/epclusa/epclusa_pi.

Follow-Up

For any additional questions, please contact Gilead Medical Information at:

☎ 1-866-MEDI-GSI (1-866-633-4474) or 🖱 www.askgileadmedical.com

Adverse Event Reporting

Please report all adverse events to:

Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or
🖱 www.gilead.com/utility/contact/report-an-adverse-event

FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or 🖱 www.accessdata.fda.gov/scripts/medwatch

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