



Northwest Portland Area
Indian Health Board
Indian Leadership for Indian Health

Medications for HCV in Pediatric Patients

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Objectives

- Recognize HCV screening recommendations for pediatrics
- Discuss available HCV medications recommended for use in pediatric patients

Updated Guidance on HCV Screening in Pediatrics



Perinatal hepatitis C is increasing

Early testing and intervention can save lives



CDC recommends:

- SCREENING** patients for hepatitis C during each pregnancy
- TESTING** all babies exposed during pregnancy with an HCV RNA at age 2-6 months
- MANAGING** infants with an HCV RNA+ test result alongside a provider with pediatric hepatitis C expertise

bit.ly/rr72041a1
November 3, 2023




MMWR. November 3, 2023. 72(4);1-19

Recommendations for Monitoring and Management

- Liver biochemistries at initial diagnosis and at least annually
 - Assess disease severity via routine laboratories
 - Assess disease progression
- Hepatitis A and B vaccinations
- Children with cirrhosis need HCC surveillance and endoscopic surveillance

<https://www.hcvguidelines.org/unique-populations/children>

Treat Children with HCV at 3 Years of Age

Recommendations for Whom and When to Treat Among Children and Adolescents With HCV Infection	
RECOMMENDED	RATING 
Direct-acting antiviral (DAA) treatment with an approved regimen is recommended for all children and adolescents with HCV infection aged ≥ 3 years as they will benefit from antiviral therapy, regardless of disease severity.	I, B
The presence of extrahepatic manifestations—such as cryoglobulinemia, rashes, and glomerulonephritis—as well as advanced fibrosis should lead to early antiviral therapy to minimize future morbidity and mortality.	I, C

<https://www.hcvguidelines.org/unique-populations/children>



Glecaprevir/Pibrentasvir



MAVYRET DOSING

8-WEEK DOSING FOR TN NC AND CC PEDIATRIC PATIENTS AS YOUNG AS 3 YEARS WITH CHRONIC HCV^{1*}

MAVYRET is dosed once daily, with food, based on body weight or age

<20 kg	≥20 to <30 kg	≥30 to <45 kg	≥45 kg or ≥12 years old
3 packets[†] (150 mg/60 mg)	4 packets[†] (200 mg/80 mg)	5 packets[†] (250 mg/100 mg)	3 tablets[‡] (300 mg/120 mg)

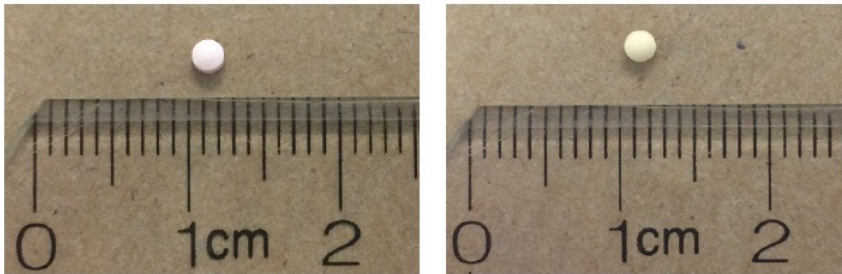
- Indicated for 8 weeks for HCV genotypes 1-6
- Approved for use in children 3 yo and above June 2021
- Taken with food

Glecaprevir/Pibrentasvir: Pediatric Dosing

Table 3: Recommended Dosage in Pediatric Patients 3 Years of Age and Older

Body Weight (kg) or Age (yrs)	Daily Dose of glecaprevir/pibrentasvir	Dosing of MAVYRET
Less than 20 kg	150 mg/60 mg per day	Three 50 mg/20 mg packets of oral pellets once daily
20 kg to less than 30 kg	200 mg/80 mg per day	Four 50 mg/20 mg packets of oral pellets once daily
30 kg to less than 45 kg	250 mg/100 mg per day	Five 50 mg/20 mg packets of oral pellets once daily
45 kg and greater OR 12 years of age and older	300 mg/120 mg per day	Three 100 mg/40 mg tablets once daily ¹ (see Recommended Dosage in Adults)

¹ Pediatric patients weighing 45 kg and greater who are unable to swallow tablets may take six 50 mg/20 mg packets of oral pellets once daily. Dosing with oral pellets has not been studied for pediatric patients weighing greater than 45 kg [see Clinical Pharmacology (12.3)].



Glecaprevir

Pibrentasvir

Source: Jonas_AASLD2021_P1551

- Sprinkle pellets on small amount of soft food with a low water content that will stick to a spoon and should be swallowed without chewing (peanut butter, chocolate hazelnut spread, cream cheese, thick jam, or Greek yogurt)
- Swallow within 15 min
- Do not crush or chew
- Do not use liquids or foods that would slide off of spoon- may cause drug to dissolve and lose effectiveness



READ STEPS 1 - 5 before you get started!

1

Find the number of packets



Mix the day's packets together with food.



About 1-2 teaspoons of an acceptable food like the ones below

Remember, if you need help, you can always call!



2

Choose the right food

USE THESE

YES Choose soft foods that stick to the spoon

IMPORTANT: If the pellets are chewed, or dissolve in the food, the medicine tastes bad and might not work.

NOT THESE

NO Watery, heated, frozen, or solid foods

<https://www.mavyret.com/content/dam/admpmavyret/documents/MAVYRET-Pediatric-Brochure.pdf>

3

Gather what you'll need



4

Prepare the dose

ADD the food to the bowl first

Be sure to get all of the pellets, and don't spill any - they're tiny!

TAP the packets so pellets fall to the bottom

PINCH above the pellets so they don't spill

CUT along the line

POUR into the bowl of food

CHECK the packets for pellets

MIX thoroughly (don't crush, or it will taste bitter)

5

Give the medication

It's important that we take this right away.

Be careful not to chew the pellets.

You can always add more food to get every last pellet to get the full dose!

Make sure to follow medication with a snack or meal.

QUESTIONS AND SAFETY INFORMATION

How long can the pellets stay in the mixture?

- **After 5 minutes**, a bitter taste will be noticeable to the child.
- **After 15 minutes**, the medication will be less effective.
Discard and call your healthcare provider.

What if my child missed a daily dose of the medication?

- Contact your healthcare provider. **Do not** give a double dose of MAVYRET.

What if my child is allergic to the recommended foods?

- Contact your healthcare provider. **Do not** mix with food that your child is allergic to.

What if my child has trouble swallowing or cannot finish the mixture?

- Contact your healthcare provider. **Do not** continue giving the mixture or give your child an additional dose of MAVYRET.

Can my child drink water after completing their dose?

- Yes. Drinking water after taking the medication will not change its effectiveness.

What if I need replacement packets?

- Contact your healthcare provider.

Please see additional Important Safety Information throughout the brochure, including Boxed Warning. Please see accompanying full **Prescribing Information**, including the **Patient Information**.

NEED HELP?



Call your healthcare provider,
call your pharmacist, call us at
877-MAVYRET (877-628-9738)
or visit www.mavyret.com

<https://www.mavyret.com/content/dam/admpmavyret/documents/MAVYRET-Pediatric-Brochure.pdf>

Sofosbuvir/Velpatasvir Oral Pellets



AUTHORIZED GENERIC OF
EPLUSA®
(SOFOSBUVIR/VELPATASVIR)

Prescribing information,
including **BOXED WARNING** ▶

BLISTER PACK

NDC: 72626-2701-1
Tablet: 400/100 mg
28 count



NDC 61958-2204-1

28 packets

Rx only

Eplusa®
(sofosbuvir and velpatasvir) oral pellets

200 mg/50 mg per packet

Pellets should be swallowed whole. Do not chew pellets.

Note to pharmacist: Do not cover ALERT box with pharmacy label.

ALERT: Find out about medicines that should NOT be taken with Eplusa



NDC 61958-2205-1

28 packets

Rx only

Eplusa®
(sofosbuvir and velpatasvir) oral pellets

150 mg/37.5 mg per packet

Pellets should be swallowed whole. Do not chew pellets.

Note to pharmacist: Do not cover ALERT box with pharmacy label.

ALERT: Find out about medicines that should NOT be taken with Eplusa



Eplusa [package insert]. Foster City, CA: Gilead Sciences, Inc.; 2016.

Administration

- 1 tablet once daily with or without food

Available as:

- 400 mg/100 mg tab
- 200 mg/50 mg tab
- 150 mg/37.5 mg pellets
- Gently mix pellets in soft, non-acidic foods (pudding, chocolate syrup, ice cream) and consume within 15 minutes or
- Swallow pellets directly without chewing

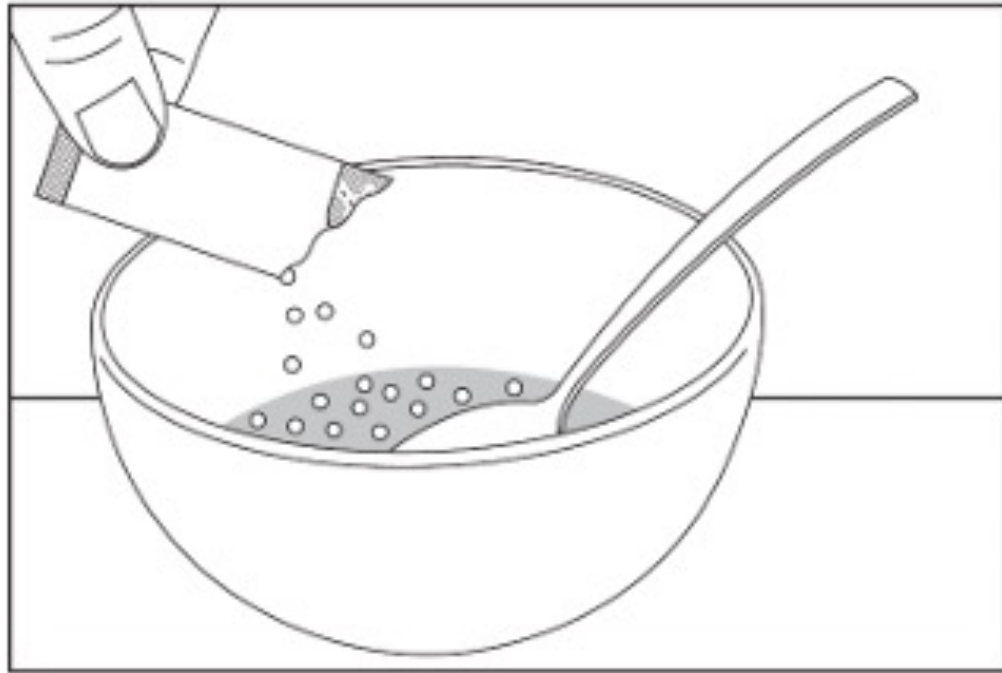


Figure F

OR

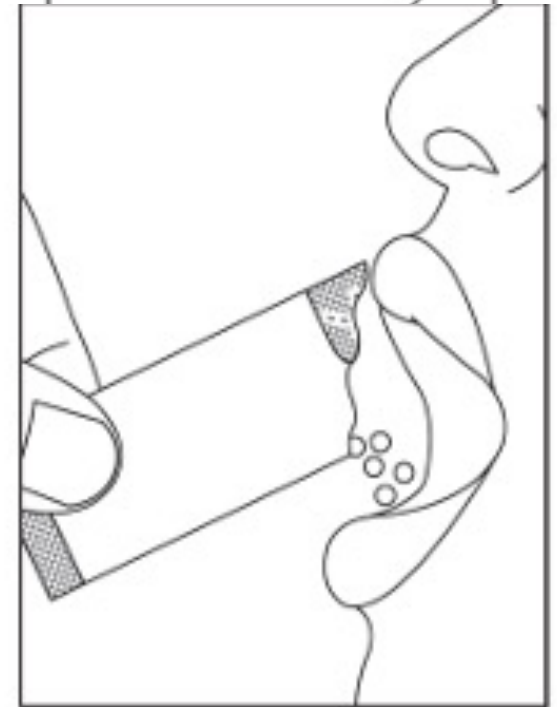


Figure G

- Gently mix pellets in soft, non-acidic foods (pudding, chocolate syrup, ice cream) and consume within 15 minutes or
- Swallow pellets directly without chewing

Sofosbuvir/Velpatasvir: Pediatric Approval

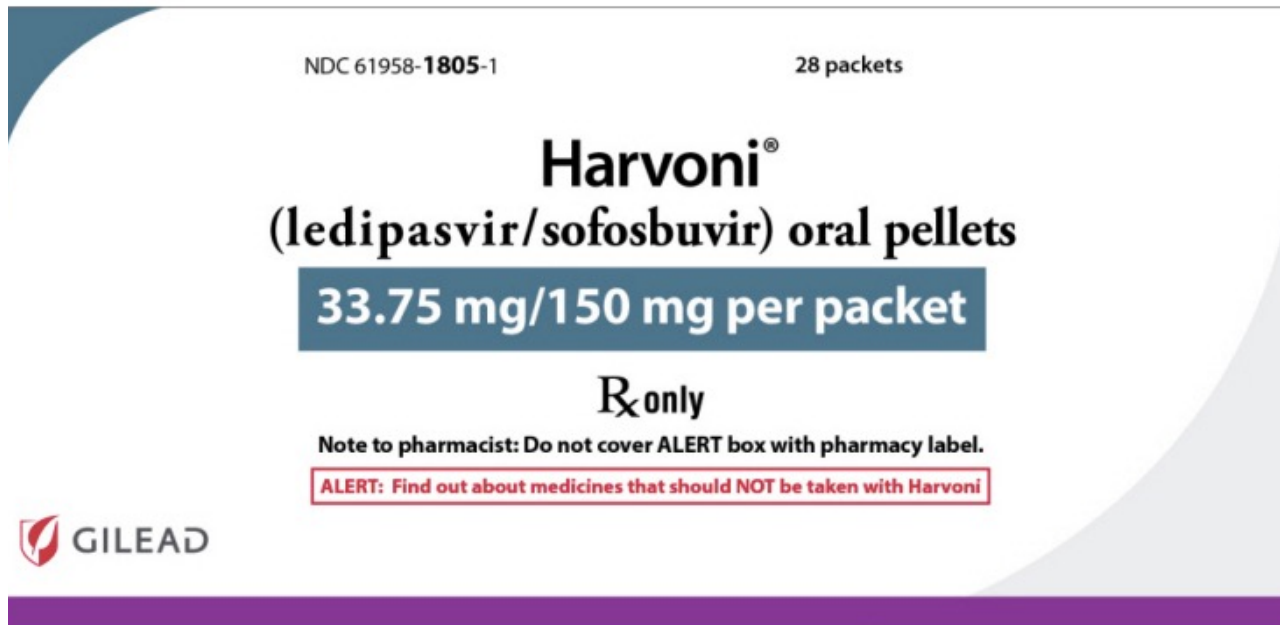
- March 2020: approved for use in children age 6 and above
- June 2021: approved for use in children age 3 and above or weighing at least 17 kg

Table 2 Dosing for Pediatric Patients 3 Years and Older with Genotype 1, 2, 3, 4, 5, or 6 HCV Using EPCLUSA Oral Pellets or Tablets

Body Weight (kg)	EPCLUSA Daily Dose	Dosing of EPCLUSA Oral Pellets	Dosing of EPCLUSA Tablet
less than 17	150 mg/37.5 mg per day	one 150 mg/37.5 mg packet of pellets once daily	N/A
17 to less than 30	200 mg/50 mg per day	one 200 mg/50 mg packet of pellets once daily	one 200 mg/50 mg tablet once daily
at least 30	400 mg/100 mg per day	two 200 mg/50 mg packets of pellets once daily	one 400 mg/100 mg tablet once daily ^a

a. Two 200 mg/50 mg tablets once daily can be used for patients who cannot swallow the 400 mg/100 mg tablet.

Ledipasvir/Sofosbuvir Pellet Formulation



- Orange pellets in packets available as: 33.7mg/150 mg or 45 mg/200 mg
- Indicated for GT 1, 4, 5 or 6 for 12 weeks
- Approved for use age 3 and above

Harvoni [package insert]. Foster City, CA: Gilead Sciences, Inc.; 2016.

Weight Based Dosing of Ledipasvir/Sofosbuvir


Body Weight	Once Daily Dose of Ledipasvir/Sofosbuvir
<17 kg	33.75 mg/150 mg
17 to <35 kg	45 mg/200 mg
≥35 kg	90 mg/400 mg per day

Hcvguidelines.org

Accessed Jan. 14, 2020

AASLD HCV Guidelines on Treatment

Recommended regimens listed by pangenotypic, evidence level and alphabetically for Treatment-Naive or Interferon-Experienced Children and Adolescents Without Cirrhosis or With Compensated Cirrhosis^a

RECOMMENDED	DURATION	RATING 
Combination of glecaprevir/pibrentasvir (weight-based dosing; see Table 1) for children aged ≥ 3 with any genotype ^b	8 weeks	I, B
Combination of sofosbuvir/velpatasvir (weight-based dosing; see Table 2) for children ≥ 3 of age with any genotype	12 weeks	I, B
Combination of ledipasvir/sofosbuvir (weight-based dosing; see Table 3) for children aged ≥ 3 years with genotype 1, 4, 5, or 6	12 weeks	I, B

^a Child-Pugh A

^b A longer duration of therapy (ie, 16 weeks) may be needed for genotype 3 interferon-experienced patients.

Hcvguidelines.org

Accessed Feb. 27, 2024

Key Points

- Pan-genotypic HCV DAAs available for children 3 years of age and older
 - Glecaprevir/pibrentasvir
 - Sofosbuvir/velpatasvir
- Ledipasvir/sofosbuvir approved for children 3 years of age and above for HCV genotype 1, 4, 5 and infections
- Pellet formulation available

Indian Country ECHO HCV

End of Presentation

Questions?



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