

FDA approves hep C drugs for kids 12 and older

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Electron micrographs of hepatitis C virus purified from cell culture. Scale bar is 50 nanometers. Credit: Center for the Study of Hepatitis C, The Rockefeller University.

(HealthDay)—The U.S. Food and Drug Administration has approved two drugs to treat hepatitis C infection in children aged 12 and older.

Both Solvaldi (sofosbuvir) and Harvoni (ledipasvir, sofosbuvir) are

already approved for use in adults, the agency said in a news release Friday.

The medications are antivirals that prevent the [hepatitis](#) C virus (HCV) from reproducing. "In most cases, they cure HCV," the FDA added.

"These approvals will help change the landscape for HCV treatment by addressing an unmet need in children and adolescents," said Dr. Edward Cox, director of the Office of Antimicrobial Products in the FDA's Center for Drug Evaluation and Research.

Hepatitis C causes liver inflammation that can lead to liver failure. Between 3 and 4 million people in the United States are infected with the virus, the agency said.

Children born to infected mothers are at higher risk of being infected, the FDA said, noting there are an estimated 23,000 to 46,000 children in the United States with hepatitis C.

In clinical studies, the most common side effects of both drugs were fatigue and headache.

People taking hepatitis C antivirals who are also infected with hepatitis B have a greater risk of serious liver problems or death. This can happen because the hepatitis B virus can be reactivated if patients are not also taking antivirals to stem the hepatitis B infection.

Harvoni and Sovaldi are marketed by Gilead Sciences Inc., in Foster City, Calif.

More information: Visit the [FDA](#) to learn more.

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