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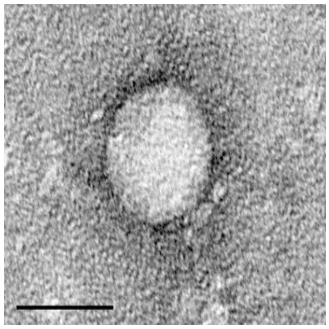
First Combination Pill Approved For Hepatitis C



The FDA has approved a new antiviral drug to treat chronic hepatitis C virus (HCV) genotype 1 infections. Harvoni from Gilead Sciences is the first combination drug (ledipasvir/sofosbuvir) for the treatment of HCV as well as the first treatment for the disease that does not require administration with interferon and ribavirin.

Edward Cox, MD, MPH, director of the Office of Antimicrobial Products in the FDA's Center for Drug Evaluation and Research, said the new drug changes the "treatment paradigm" for patients with HCV. "Until last year, the only available treatments for HCV required administration with interferon and ribavirin," Dr Cox said in a news release. "Now, patients and health care professionals have multiple treatment options, including a combination pill to help simplify treatment regimens."

Though a novel combination, this drug is associated with a bit of controversy. Sovaldi (sofosbuvir) has been previously approved and is considered to be one of the most expensive drugs available. It costs around $84,000 for a 12-week course of treatment. That translates into a cost of $1,000 per pill. It is believed that the combination drug will cost even more. Although the price is still unknown, the manufacturer's Executive Vice President of Corporate and Medical Affairs has revealed that it would be in the range of $95,000.

The drug has been approved on the basis of three clinical trials. The first trial was comprised of patients who had never been treated for their infection; the second one included patients similar to the first trial but some had cirrhosis; while the third one had patients with infection and some with cirrhosis who had not responded to previous treatment. A total of 1,518 patients with HCV participated in the three trials and all were randomly assigned to receive the combination drug with or without ribavirin.

In all three trials, the results were in favour of the drug. Approximately 90 percent of participants who took the new combination drug achieved sustained virologic response. By 12 weeks, HCV was no longer detectable in their bloodstreams. In the first trial, 94 percent of treatment-naive participants demonstrated a sustained virologic response in eight weeks. The FDA reports that in all the three trials, ribavirin did not increase response rates in the participants.

The most common side effects associated with the drug include fatigue and headache. The drug has also been recommended for approval in the European Union by the Committee for Medicinal Products for Human Use of the European Medicines Agency.

Source: Medscape

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