FDA Update; New Dosage Forms Approved Sovaldi and Harvoni Children Ages 3 to 12

September 4, 2019, the U.S. FDA released their recent approval of new dosage forms of Sovaldi and Harvoni for children 3 to 12 years of age.

September 18, 2019 By Connie M. Welch

Sovaldi

Sovaldi can be used for children 3-12 years with genotype 2 or 3 without cirrhosis or with compensated cirrhosis with treatment including ribavirin.

Treatment Length

Genotype 2: Treatment of Sovaldi + Ribavirin is 12 weeks.

Genotype 3: Treatment of Sovaldi + Ribavirin is 24 weeks.

Note: Sovaldi & Ribavarin are available in oral tablets or pellets taken daily based on weight. Taken with or without food. Sovaldi pellets can be taken who cannot swallow the tablet form.

Side Effects

Side effects were reported with a clinical trial to be the same as adults which include; tiredness and headache. Decreased appetite was also observed.

Cure Rate

Cure rate for children 12 years and younger, with genotype 2 and 3 was reported 100% for both with no failure or relapse.

Cure rate for children 3 to 6 years, with the median age being 4 years, cure rate was 80% for those with genotype 2 and 100% for those with genotype 3, with no failure or relapse.

See full treatment details: U.S. FDA Approval for new label changes with Sovaldi for Children 3 to 12 years old.

Harvoni

Harvoni is approved for children 3 years and older as follows;

Genotype 1, 4, 5, or 6 without cirrhosis or with compensated cirrhosis (Child-Pugh A).

Genotype 1 with decompensated cirrhosis, including treatment with ribavirin.

Genotype 1 or 4 who are liver transplant recipients without cirrhosis or with compensated cirrhosis including treatment with ribavirin.

Treatment Length

Genotype 1 with no treatment experience or with compensated cirrhosis (Child-Pugh A), treatment is for 12 weeks. For treatment-experienced patients without cirrhosis, treatment is for 12 weeks. For patients with treatment experience with compensated cirrhosis (Child-Pugh A), treatment is for 24 weeks. For non-treatment experience and those with treatment experience with decompensated cirrhosis (Child-Pugh B or C) treatment is Harvoni + Ribavirin for 12 weeks.

Genotype 1 or 4 with no treatment experience or treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A), treatment with Harvoni + Ribavirin for 12 weeks.

Genotype 4, 5, or 6 with no treatment experience or treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A), treatment with Harvoni for 12 weeks.

Note: Harvoni is available in oral tablets or oral pellets taken daily based on weight. Taken with or without food. Harvoni pellets can be taken who cannot swallow the tablet form.

Side Effects

Side effects were reported with a clinical trial to be the same as adults which include; tiredness and headache. Less common side effects reported in clinical trials with adults to be the same as children include diarrhea, nausea, and insomnia.

Cure Rate

For children 6 to 12 years old cure rate was 99% with genotype 1, and 100% with genotype 4.

For children 3 to 6 years old cure rate was 97% with genotype 1 and genotype 4.

See full treatment details: U.S. FDA Approval for new label changes with Harvoni for Children 3 to 12 years old.

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