Harvoni - (90MG;400MG, 45MG;200MG ; Tablet)

Generic Name	Sofosbuvir, LEDIPASVIR	**Innovator**	Gilead
Dosage	90MG;400MG, 45MG;200MG ; Tablet	**Branded US Sales**	Less Than $1000 mn
Probable FTF	None	**Known Para IV Filers**	None
Other ANDA developers	Less Than 5	**Tentative Approvals**	None
Final Approvals	None	**Generic Launches**	None
Indication	HARVONI is a fixed-dose combination of ledipasvir, a hepatitis C virus (HCV) NS5A inhibitor, and sofosbuvir, an HCV nucleotide analog NS5B polymerase inhibitor, and is indicated for the treatment of chronic hepatitis C virus (HCV) in adults and pediatric patients 3 years of age and older: • Genotype 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis • Genotype 1 infection with decompensated cirrhosis, in combination with ribavirin • Genotype 1 or 4 infection who are liver transplant recipients without cirrhosis or with compensated cirrhosis, in combination with ribavirin.		
Complexities	Yes		

Chronology Of Events

Please Contact contact@researchdelta.com to get Detailed Information.

Executive Summary

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Patent Status

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Launch Timelines and Competition

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Chronology Of Events

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Harvoni - (33.75MG;150MG/PACKET,45MG;200MG/PACKET ; Pellets)

Generic Name	Sofosbuvir, LEDIPASVIR	**Innovator**	Gilead
Dosage	33.75MG;150MG/PACKET,45MG;200MG/PACKET ; Pellets	**Branded US Sales**	Less Than $1000 mn
Probable FTF	None	**Known Para IV Filers**	None
Other ANDA developers	Less Than 5	**Tentative Approvals**	None
Final Approvals	None	**Generic Launches**	None
Indication	HARVONI is a fixed-dose combination of ledipasvir, a hepatitis C virus (HCV) NS5A inhibitor, and sofosbuvir, an HCV nucleotide analog NS5B polymerase inhibitor, and is indicated for the treatment of chronic hepatitis C virus (HCV) in adults and pediatric patients 3 years of age and older: • Genotype 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis • Genotype 1 infection with decompensated cirrhosis, in combination with ribavirin • Genotype 1 or 4 infection who are liver transplant recipients without cirrhosis or with compensated cirrhosis, in combination with ribavirin.		
Complexities	Yes		

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