HOSPITAL PHARMACY ADMINISTRATION

HPA Newsletter

Volume III, Issue I October 2016

# Influenza Virus Vaccines For 2016-2017

## (Recent FDA, CDC Updates)

**Special points of interest:**

- Latest disease updates
- Latest drugs updates

**Inside this issue:**



There are four types of influenza viruses: A, B, C and D. Human influenza A and B viruses cause seasonal epidemics of disease almost every winter in the United States. The emergence of a new and very different influenza A virus to infect people can cause an influenza pandemic. Influenza type C infections generally cause a mild respiratory illness and are not thought to cause epidemics. Influenza D viruses primarily affect cattle and are not known to infect or cause illness in people.

Influenza A viruses are divided into subtypes based on two proteins on the surface of the virus: the hemagglutinin (H) and the neuraminidase (N). There are 18 different hemagglutinin subtypes and 11 different neuraminidase subtypes. (H1 through H18 and N1 through N11 respectively.)

Influenza B viruses are not divided into subtypes, but can be further broken down into lineages and strains. Currently circulating influenza B viruses belong to one of two lineages: B/Yamagata and B/Victoria.

Influenza A (H1N1), A (H3N2), and one or two influenza B viruses (depending on the vaccine) are included in each year's influenza vaccine. The seasonal flu vaccine does not protect against influenza C viruses. In addition, flu vaccines will NOT protect against infection and illness caused by other viruses that also can cause influenza-like symptoms. There are many other non-flu viruses that can result in influenza-like illness (ILI) that spread during flu season. [1]

Flu viruses constantly change, or mutate, as they circulate in nature. Seasonal influenza vaccines need to be updated each year to match new emerging strains. Scientists monitor flu strains circulating around the globe to predict which 3 or 4 strains will be most prevalent during the next flu season. To allow enough time for the vaccine to be made, the strains must be selected more than 6 months before the influenza season begins. Sometimes, an unexpected strain predominates or emerges too late to be included in the vaccine. [2]

### What's new this flu season? [3,4]

- Only injectable flu shots are recommended for use this season.
- The recommendations for vaccination of people with egg allergies have changed:-

*The recommendations for people with egg allergies have been updated for this season.*

*People who have experienced only hives after exposure to egg can get any licensed flu vaccine that is otherwise appropriate for their age and health.*

*People who have symptoms other than hives after exposure to eggs, such as angioedema, respiratory distress, lightheadedness, or recurrent emesis; or who have needed epinephrine or another emergency medical intervention, also can get any licensed flu vaccine that is otherwise appropriate for their age and health, but the vaccine should be given in a medical setting and be supervised by a health care provider who is able to recognize and manage severe allergic conditions. (Settings include hospitals, clinics, health departments, and physician offices). People with egg allergies no longer have to wait 30 minutes after receiving their vaccine.*

- On June 22, 2016, CDC's Advisory Committee on Immunization Practices (ACIP) voted that the live attenuated influenza vaccine (LAIV) should not be used during the 2016-2017 flu season .


- Flu vaccines have been updated to better match circulating viruses :-

*FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) met in Silver Spring, Maryland, on March 4, 2016, to select the influenza viruses for the composition of the influenza vaccine for the 2016-2017 U.S. influenza season. During this meeting, the advisory committee reviewed and evaluated the surveillance data related to epidemiology and antigenic characteristics of recent influenza isolates, serological responses to 2015-2016 vaccines, and the availability of candidate strains and reagents.*

*The committee recommended that the trivalent formulation influenza vaccines for the U.S. 2016-2017 influenza season contain the following:*

* *an A/California/7/2009 (H1N1)-like virus;*
* *an A/Hong Kong /4801/2014 (H3N2)-like virus*
* *a B/Brisbane/60/2008-like virus (B/Victoria lineage).*

*The committee also recommended that quadrivalent influenza vaccines contain the above three strains and the following additional B strain:*

* *a B/Phuket/3073/2013-like virus (B/Yamagata lineage)*

# When and How should I get vaccinated ?

- Getting an annual flu vaccine is the first and best way to protect yourself and your family from the flu. Flu vaccination can reduce flu illnesses, doctors' visits, and missed work and school due to flu, as well as prevent flu-related hospitalizations. The more people who get vaccinated, the more people will be protected from flu, including older people, very young children, pregnant women and people with certain health conditions who are more vulnerable to serious flu complications.
- CDC recommends a yearly flu vaccine for everyone 6 months of age and older as the first and most important step in protecting against this serious disease by the end of October, if possible and should continue throughout the flu season, even in January or later.
- Some children 6 months through 8 years of age will require two doses of flu vaccine for adequate protection from flu. Children in this age group who are getting vaccinated for the first time will need two doses of flu vaccine, spaced at least 28 days apart.
- Children younger than 6 months are at higher risk of serious flu complications, but are too young to get a flu vaccine. Because of this, safeguarding them from flu is especially important. If you live with or care for an infant younger than 6 months of age, you should get a flu vaccine to help protect them from flu. Also, studies have shown that getting the flu vaccine during pregnancy can protect the baby after birth for several months [5]

## References:

1- Types of Influenza Viruses| Seasonal Influenza (Flu) | CDC [Internet]. Cdc.gov. 2016 [cited 25 September 2016]. (Click Here)

2- Strategy may improve seasonal flu vaccines [Internet]. National Institutes of Health (NIH). 2016 [cited 25 September 2016]. (Click Here)

3- Influenza Virus Vaccine for the 2016-2017 Season [Internet]. Fda.gov. 2016 [cited 25 September 2016]. (Click Here)

4. What You Should Know for the 2016-2017 Influenza Season [Internet]. Centers for Disease Control and Prevention. 2016 [cited 25 September 2016]. (Click Here)

5. What You Should Know for the 2016-2017 Influenza Season [Internet]. Centers for Disease Control and Prevention. 2016 [cited 25 September 2016]. (Click Here)

# Harvoni

## The Latest Treatment for Hepatitis C

On 6th of December 2013, FDA announced Sovaldi may be used for Hepatitis C patients. The majority of doctors and patients alike welcomed the new medicine with high cure rate and mild side effects. However, it was largely known that Gilead is working on an even better than Sovaldi medicine – Harvoni. Therefore, many patients did not receive Sovaldi treatment because Harvoni, the better solution, was on the way. On 10th of October 2014, less than a year after Sovaldi launch, Harvoni got FDA approval. From now on, a large majority of Hepatitis C patients are receiving Harvoni as the first choice of treatment.

**Cost, insurance coverage, and availability**

Harvoni is typically more expensive than Sovaldi. Harvoni combines the drug found in Sovaldi (sofosbuvir) with another drug (ledipasvir) in one tablet. Sovaldi only contains sofosbuvir. It must be taken with other drugs. This increases the total cost of treatment.

**Harvoni and Sovaldi are very effective :**

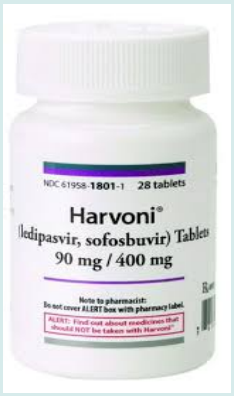
- **SVR12 for Treatment-Naïve Subjects with Genotype 1 or 4 HCV is 96% .**
- **SVR12 rates were 94% (63/67) in subjects with cirrhosis and 98% (46/47) in subjects who were previously-treated and had cirrhosis.**

**Harvoni is a direct-acting antiviral (DAA) medication. DAAs are a group of medications that directly block the ability of the hepatitis C virus to make copies of itself.**

**Harvoni is a combination of two DAAs. One is Sofosbuvir, which is a nucleotide polymerase inhibitor, and the other is ledipasvir, which is an NS5A inhibitor.**

Sofosbuvir interferes with the reproduction of the virus's genetic material, stopping the production of new hepatitis C virus. Ledipasvir works by interfering with a protein needed to complete the hepatitis C virus life cycle in the liver cell.

Hepatitis C treatment can cure a person from Hepatitis C. However, a person could get infected again[1]




INDICATIONS AND USAGE:

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) genotype 1, 4, 5 or 6 infection.

DOSAGE AND ADMINISTRATION:

Recommended dosage: One tablet (90 mg of ledipasvir and 400 mg of sofosbuvir) taken orally once daily with or without food.

CONTRAINDICATIONS :

If HARVONI is administered with ribavirin, the contraindications to ribavirin also apply to this combination regimen. Refer to the ribavirin prescribing information for a list of contraindications for ribavirin.


WARNINGS AND PRECAUTIONS :

- **Serious Symptomatic Bradycardia When Coadministered with Amiodarone**

  Post marketing cases of symptomatic bradycardia, as well as fatal cardiac arrest and cases requiring pacemaker intervention, have been reported when amiodarone is Coadministered with HARVONI. Bradycardia has generally occurred within hours to days, but cases have been observed up to 2 weeks after initiating HCV treatment.

  Patients also taking beta blockers, or those with underlying cardiac comorbidities and/or advanced liver disease

  , may be at increased risk for symptomatic bradycardia with coadministration of amiodarone. Bradycardia generally resolved after discontinuation of HCV treatment.

Globally, approximately 20% of all hepatitis C infections are caused by genotype 4. In addition, genotype 4 is the dominant HCV genotype in Egypt.

The following key studies were used to support the recommendations for treatment of patients with chronic hepatitis C and genotype 4 infection :


## 1- Study 1119: [2,3,4]

To evaluate the Efficacy and Safety of Sofosbuvir/Ledipasvir Fixed-Dose Combination in Treatment-Naive and Treatment-Experienced Subjects With Chronic Genotype 4 or 5 HCV Infection.

HARVONI was administered for 12 weeks to treatment-naïve and previously-treated subjects with genotype 4 HCV infection

**Results:**

- In Study 1119, the overall SVR12 rate was 93% (41/44). Rates were similar for treatment naïve and experienced patients and for those with and without cirrhosis.

**Conclusion:**

LDV/SOF for 12 weeks represents a safe and effective all–oral treatment for patients with GT4 HCV. [2,3,4]

## 2– Study ION 4

To evaluate the safety and efficacy of 12 weeks of treatment with Harvoni without ribavirin in HCV treatment-naïve and previously-treated subjects with genotype 1 or 4 HCV infection who were co-infected with HIV-1.

**Results:**

-In ION-4, all 8 subjects achieved SVR12.
-SVR12 rates were 94% (63/67) in subjects with cirrhosis and 98% (46/47) in subjects who were previously-treated and had cirrhosis. The relapse rate in the ION -4 trial in Black subjects was 9% (10/115), all of whom were IL28B non-CC genotype, and none in non-Black subjects (0/220). In the ION-1, ION-2, and ION-3 HCV mono-infection studies, relapse rates were 3% (10/305) in Black subjects and 2% (26/1637) in non-Black subjects.

-No subject had HIV-1 rebound during the study. The percentage of CD4+ cells did not change during treatment. Median CD4+ cell count increase of 29 cells/mm3 was observed at the end of treatment with Harvoni for 12 weeks.

Hepatitis C virus (HCV) infection is a serious health problem that affects an estimated 130–170 million persons globally and results in an estimated 700,000 deaths annually

**Conclusion:**

Ledipasvir and sofosbuvir for 12 weeks provided high rates of sustained virologic response in patients coinfected with HIV-1and HCV genotype 4. [2,3,4,5]

## Refrences:

1- Harvoni (ledipasvir + sofosbuvir) [Internet]. Catie.ca. 2016 [cited 29 September 2016]. (Click Here)

2- FULL PRESCRIBING INFORMATIONOF HARVONI [Internet]. a.fda.gov. 2016 [cited 29 September 2016]. (Click Here)

3- Harvoni - FDA prescribing information, side effects and uses [Internet]. Drugs.com. 2016 [cited 29 September 2016]. (Click Here)

4- Efficacy and Safety of Ledipasvir/Sofosbuvir Fixed-Dose Combination in Treatment-Naive and Treatment-Experienced Subjects With Chronic Genotype 4 or 5 HCV Infection - Study Results - ClinicalTrials.gov [Internet]. Clinicaltrials.gov. 2016 [cited 29 September 2016]. (Click Here)

5- Ledipasvir - Sofosbuvir in GT1 or GT4 and HIV Coinfection ION - 4 [Internet]. hcvonline.org. 2016 [cited 29 September 2016]. (Click Here)

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# Our Newsletter

The Hospital Pharmacy Administration Newsletter aims to publicize up-to-date news, information, resources, and recent healthcare topics that have an impact on the patient's quality of care in addition to practices serving physicians and pharmacists. A main goal of this publication is to send our news and updates on health care drug related issues, recently reported and have direct impact on Clinical and Hospital Pharmacy practice in Egypt.

# Hospital Pharmacy Administration (HPA)

## Vision

To implement and spread clinical awareness among our hospital pharmacists to ensure better patient quality of care.

## Mission

To manage and assure that hospital pharmacists meet each individual patient's drug-related needs through provision of pharmaceutical care services.

## Goals and Objectives

Increase awareness of hospital Pharmacists on the importance of applying clinical knowledge in their pharmacy practice through:

- Plotting an appropriate pharmaceutical care plan for each patient according to his medication use strategy.
- Helping healthcare team through promptly responding to drug information requests.
- Integrating patient counseling into the process of dispensing.

# NO HARMe

**NO HARMe** is a national voluntary medication error and 'near miss' reporting program founded for the purpose of sharing the learning experiences from medication errors. Implementation of preventative strategies and system safeguards to decrease the risk for error-induced injury and thereby promote medication safety in healthcare is our collaborative goal.

**NO HARMe guarantees confidentiality and security of information received**

To report a medication error to NO HARMe:

- Visit our website: www.eda.mohealth.gov.eg or,
- Email us at: medication.errors.system@gmail.com

**WHEREVER THE ART OF MEDICINE IS LOVED, THERE IS ALSO A LOVE FOR HUMANITY**