NATIONAL PBM BULLETIN

January 26, 2018

DEPARTMENT OF VETERANS AFFAIRS
PHARMACY BENEFITS MANAGEMENT SERVICES (PBM), MEDICAL ADVISORY PANEL (MAP),
VISN PHARMACIST EXECUTIVES (VPEs), AND THE CENTER FOR MEDICATION SAFETY (VA MedSAFE)

Potential for Look-Alike/Sound-Alike (LA/SA) Confusion between Sofosbuvir/Velpatasvir (Epclusa®) and Sofosbuvir/Velpatasvir/Voxilaprevir (Vosevi®) in Patients with Hepatitis C Virus (HCV) Infection

I. ISSUE

One VA medical center (VAMC) reported a medication error involving Look-Alike/Sound-Alike (LA/SA) confusion between sofosbuvir 400 mg/velpatasvir 100 mg (Epclusa®) and sofosbuvir 400 mg/velpatasvir 100 mg/**voxilaprevir** 100 mg (Vosevi®) that resulted in a sentinel event.

II. BACKGROUND

Sofosbuvir/velpatasvir (Epclusa®) is a fixed-dose combination of a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor and an HCV NS5A inhibitor, respectively, and is indicated for the treatment of adult patients with chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection:

- without cirrhosis or with compensated cirrhosis (Child-Pugh A);
- with decompensated cirrhosis (Child-Pugh B or C) for use in combination with ribavirin.

Sofosbuvir/velpatasvir/voxilaprevir (Vosevi®) is a fixed-dose combination of a HCV nucleotide analog NS5B polymerase inhibitor, an HCV NS5A inhibitor, and an HCV NS3/4A protease inhibitor, respectively, for the treatment of adult patients with chronic HCV infection without cirrhosis or with compensated cirrhosis (Child-Pugh A only; contraindicated in decompensated cirrhosis) who have:

- genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor.
- genotype 1a or 3 infection and have previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor. Additional benefit of sofosbuvir/velpatasvir/voxilaprevir over sofosbuvir/velpatasvir was not shown in adults with genotype 1b, 2, 4, 5, or 6 infection previously treated with sofosbuvir without an NS5A inhibitor.

III. DISCUSSION

Factors that may contribute to LA/SA confusion include:

- Same indication and genotypes addressed.
  - Both agents are indicated for the treatment of adult patients with chronic HCV.
  - Both agents treat genotype 1, 2, 3, 4, 5, or 6 infection.
- Shared components within the fixed-dose combination.
  - One tablet of Epclusa® contains 400 mg of sofosbuvir and 100 mg of velpatasvir.
  - One tablet of Vosevi® contains 400 mg of sofosbuvir and 100 mg of velpatasvir, as well as 100 mg of voxilaprevir.
- Same dosing regimen and duration.
  - One tablet orally once daily with or without food for 12 weeks for sofosbuvir/velpatasvir (Epclusa®).
  - One tablet orally once a day with food for 12 weeks for sofosbuvir/velpatasvir/voxilaprevir (Vosevi®).
- Both are tablets.
- Both are packaged in white bottles with similar design and coloring, each containing 28 tablets. See Figures 1 and 2 on page 2.

(continued on page 2)

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Alerts are based on the clinical evidence available at the time of publication. Recommendations are intended to assist practitioners in providing consistent, safe, high quality, and cost effective drug therapy. They are not intended to interfere with clinical judgment. When using dated material, the clinician should consider new clinical information, as available and applicable.

Potential for Look-Alike/Sound-Alike (LA/SA) Confusion between Sofosbuvir/Velpatasvir (Epclusa®) and Sofosbuvir/Velpatasvir/Voxilaprevir (Vosevi®) in Patients with Hepatitis C Virus (HCV) Infection

(continued from page 1)

Figure 1. Sofosbuvir/velpatasvir (Epclusa®) bottle and tablets.

Figure 2. Sofosbuvir/velpatasvir/voxilaprevir (Vosevi®) bottle and tablets.

Notable differences between the two products include:

- Appearance in tablet shape, color, and imprints.
  - Sofosbuvir/velpatasvir (Epclusa®) tablets are pink, diamond-shaped, film-coated, debossed with "GSI" on one side and "7916" on the other. See Figure 1.
  - Sofosbuvir/velpatasvir/voxilaprevir (Vosevi®) tablets are beige, capsule-shaped, film-coated, and debossed with "GSI" on one side and " 3 " on the other side. See Figure 2.
- Use in patients with moderate or severe hepatic impairment.
  - Sofosbuvir/velpatasvir (Epclusa®) has dosing options for patients with compensated (Child-Pugh A) or decompensated cirrhosis (Child-Pugh B or C).
  - On the other hand, sofosbuvir/velpatasvir/voxilaprevir (Vosevi®) is not recommended in patients with moderate or severe hepatic impairment (Child-Pugh B or C) due to higher exposures of voxilaprevir in these patients.

IV. PBM AND VA MEDSAFE RECOMMENDATIONS include:

- Pharmacy should review their stock of sofosbuvir/velpatasvir (Epclusa®) and sofosbuvir/velpatasvir/voxilaprevir (Vosevi®) to ensure that a method is in place to distinguish between the two agents in order to avoid potential LA/SA confusion (i.e., warning stickers/labels, separate product placement on shelves).
- Pharmacy should build software alerts to warn about possible LA/SA confusion between sofosbuvir/velpatasvir (Epclusa®) and sofosbuvir/velpatasvir/voxilaprevir (Vosevi®).
- Pharmacy can take the following steps inside VA's computerized drug-order entry system to reduce potential look-alike error with these orthographically similar generic names:
  - Add a short descriptor (less than 74 characters) to "Display Restriction/Guidelines". As blue line text, this descriptor displays as dialog and does not become part of order. See Figure 3 on page 3.
  - Facilities may build an order check (CROC) that prompts confirmation of which product was selected.

(continued on page 3)

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(continued from page 2)

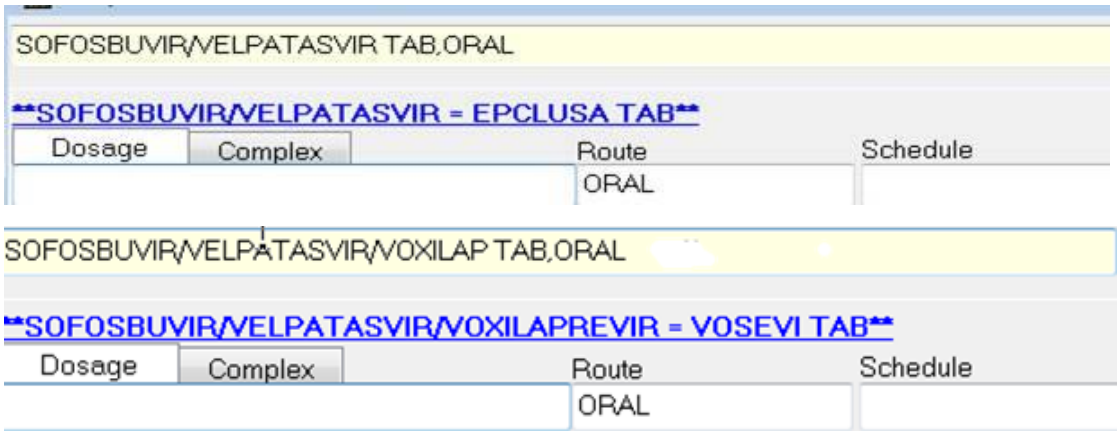

Figure 3. Examples of blue line text.

V. REFERENCES

1. Internal data.
2. EPCLUSA® (sofosbuvir and velpatasvir) tablets, for oral use [prescribing information].Foster City, CA: Gilead Sciences, Inc. August 2017.
3. VOSEVI® (sofosbuvir, velpatasvir, and voxilaprevir) tablets, for oral use [prescribing information]. Foster City, CA: Gilead Sciences, Inc. July 2017.

ACTIONS

- ***Facility Director*** *(or physician designee): Forward this document to the Facility Chief of Staff (COS).*
- ***Facility COS and Chief Nurse Executives:*** *Forward this document to all appropriate providers and health care staff (e.g.,* ***primary care providers, infectious disease providers, and pharmacy staff, including contract providers, etc****.). In addition, forward to the Associate Chief of Staff (ACOS) for Research and Development (R&D). Forward to other VA employees as deemed appropriate.*
- ***ACOS for R&D:*** *Forward this document to Principal Investigators (PIs) who have authority to practice at the facility and to your respective Institutional Review Board (IRB).*