Saudi Pharmaceutical Industries &
Medical Appliances Corporation
Saudi Joint Stock Company
Capital S.R. 1.200.000.000

سبيماكو الدوائية
SPIMACO ADDWAEIH

الشركة السعودية للصناعات الدوائية
والمستلزمات الطبية
شركة مساهمة سعودية
رأس المال ١,٢٠٠,٠٠٠,٠٠٠ ريال

1438/04/17 – 2017/01/15 17/MS/د ت/007

**Direct Healthcare Professional Communication of Special warnings and precautions for Levera® (Daclatasvir) Film-coated tablets use. Cases of severe bradycardia and heart block have been observed when LEVERA (Daclatasvir) is used in combination with sofosbuvir and concomitant amiodarone with or without other drugs that lower heart rate.**

**"Levera® Film-coated tablets"**
**Daclatasvir**

**Dear Healthcare Professional,**

SPIMACO would like to inform you about of Special warnings and precautions for **Levera® (Daclatasvir)** Film-coated tablets use. Cases of severe bradycardia and heart block have been observed when LEVERA is used in combination with sofosbuvir and concomitant amiodarone with or without other drugs that lower heart rate. The mechanism is not established.

**Information on the safety Concern**

Cases of severe bradycardia and heart block have been observed when LEVERA is used in combination with sofosbuvir and concomitant amiodarone with or without other drugs that lower heart rate. The mechanism is not established.

The concomitant use of amiodarone was limited through the clinical development of sofosbuvir plus direct-acting antivirals (DAAs). Cases are potentially life threatening, therefore amiodarone should only be used in patients on LEVERA and sofosbuvir when other alternative antiarrhythmic treatments are not tolerated or are contraindicated.

Should concomitant use of amiodarone be considered necessary it is recommended that patients are closely monitored when initiating LEVERA in combination with sofosbuvir. Patients who are identified as being at high risk of bradyarrhythmia should be continuously monitored for 48 hours in an appropriate clinical setting.

Due to the long half-life of amiodarone, appropriate monitoring should also be carried out for patients who have discontinued amiodarone within the past few months and are to be initiated on LEVERA in combination with sofosbuvir.

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All patients receiving LEVERA and sofosbuvir in combination with amiodarone with or without other drugs that lower heart rate should also be warned of the symptoms of bradycardia and heart block and should be advised to seek medical advice urgently should they experience them.

**The information in this letter has been approved by the Saudi Food and Drug Authority.**

The Summary of Products Characteristics (SPC) and Patient Information Leaflet (PIL) of "**Levera ®**" (Daclatasvir) in Saudi Arabia were updated to reinforce the safety of treated patients.

**Call for reporting**

As a reminder, there is a need to report any suspected adverse reactions to the National Pharmacovigilance and Drug Safety Center (NPC):

- Fax: +966-11-205-7662
- E-mail: npc.drug@sfda.gov.sa
- Online: http://ade.sfda.gov.sa/

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Yours sincerely,

15 01 2017

**PH. SATTAM AL-GHODYYR**
Pharmacovigilance Unit Manager

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