אוקטובר 2020

רופא/ה רוקח/ת נכבד/ה,

חברת סאנופי-אוונטיס ישראל בע"מ מבקשת להודיע על עדכון **העלון לצרכן והעלון לרופא** של התכשיר:

PLAVIX 75 mg, *film coated tablets.*

החומר פעיל:

Clopidogrel (as hydrogen sulfate)

ההתוויה המאושרת:

Secondary prevention of atherotrombotic events
Clopidogrel is indicated in:

- Adult Patients suffering from myocardial infarction (from a few days until less than 35 days), ischaemic stroke (from 7 days until less than 6 months) or established peripheral arterial disease.
- Adult Patients suffering from Acute Coronary Syndrome
  - Non-ST segment elevation acute coronary syndrome (unstable angina/non-Q-wave myocardial infarction (MI)), including patients undergoing a stent placement following percutaneous coronary intervention, in combination with acetylsalicylic acid (ASA).
  - ST segment elevation acute myocardial infarction, in combination with ASA in medically treated patients eligible for thrombolytic therapy

Prevention of atherothrobmotic and thromboembolic events in atrial fibrillation
In adult patients with atrial fibrillation who have at least one risk factor for vascular events, are not suitable for the treatment with Vitamin K antagonists (VKA) Anti-Thrombin or Anti Factor Xa, and who have a low bleeding risk, clopidogrel is indicated in combination with ASA for the prevention of atherothrombotic and thromboembolic events, including stroke.

בנוסף לעדכון ההתוויה, מפורטים להלן תתי הסעיפים בהם נעשו העדכונים העיקריים בעלונים.

עדכונים בעלון לרופא:

4. CLINICAL PARTICULARS

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4.4 Special warnings and precautions for use

Bleeding and haematological disorders

Due to the risk of bleeding and haematological adverse reactions, blood cell count determination and/or other appropriate testing should be promptly considered whenever clinical symptoms

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suggestive of bleeding arise during the course of treatment (see section 4.8). As with other antiplatelet agents, clopidogrel should be used with caution in patients who may be at risk of increased bleeding from trauma, surgery or other pathological conditions and in patients receiving treatment with ASA, heparin, glycoprotein IIb/IIIa inhibitors or non-steroidal anti-inflammatory drugs (NSAIDs) including Cox-2 inhibitors, or selective serotonin reuptake inhibitors (SSRIs), or CYP2C19 strong inducers or other medicinal products associated with bleeding risk such as pentoxifylline (see section 4.5). Patients should be followed carefully for any signs of bleeding including occult bleeding, especially during the first weeks of treatment and/or after invasive cardiac procedures or surgery. The concomitant administration of clopidogrel with oral anticoagulants is not recommended since it may increase the intensity of bleedings (see section 4.5).

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Cytochrome P450 2C19 (CYP2C19)

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Use of medicinal products that induce the activity of CYP2C19 would be expected to result in increased drug levels of the active metabolite of clopidogrel and might potentiate the bleeding risk. As a precaution concomitant use of strong CYP2C19 inducers should be discouraged (see section 4.5).

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4.5 Interaction with other medicinal products and other forms of interaction

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Other concomitant therapy:

Inducers of CYP2C19
Since Clopidogrel is metabolized to its active metabolite partly by CYP2C19, use of medicinal products that induce the activity of this enzyme would be expected to result in increased drug levels of the active metabolite of clopidogrel.

Rifampicin strongly induces CYP2C19, resulting in both an increased level of clopidogrel active metabolite and platelet inhibition, which in particular might potentiate the risk of bleeding. As a precaution, concomitant use of strong CYP2C19 inducers should be discouraged (see section 4.4).

עדכונים בעלון לצרכן:

2. לפני השימוש בתרופה

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תגובות בין תרופתיות:

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○ ריפאמפיצין (משמש לטיפול בזיהומים חמורים)

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השינויים המודגשים ברקע צהוב מהווים החמרה. כמו כן, בוצעו שינויים נוספים הכוללים תוספת מידע, השמטת מידע ועדכוני נוסח שאינם מהווים החמרה.

העלונים המעודכנים נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות . בנוסף ניתן לקבלם מודפסים על ידי פנייה לבעל הרישום, סאנופי-אוונטיס ישראל בע"מ, רח' בני גאון 10 נתניה או בטלפון : 09-8633700 .להלן הקישור לאתר משרד הבריאות :
https://data.health.gov.il/drugs/index.html#!/byDrug

בברכה,

צליל גנר להב

רוקחת ממונה

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