



אפריל 2022

### Plavix 75mg Film coated tablets

חומר פעיל:

Clopidogrel (as hydrogen sulfate) 75mg

ההתוויה המאושרת:

#### Secondary Prevention of atherothrombotic 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 atherothrombotic 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.

חברת סאנופי אוונטיס מבקשת להודיע על עדכון העלון לרופא והעלון לצרכן.

העדכונים העיקריים הינם:

**בעלון לרופא:**

#### 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 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). **Due to the increased risk of haemorrhage, triple antiplatelet therapy (clopidogrel + ASA + dipyridamole) for stroke secondary prevention is not recommended in patients with acute non-cardioembolic ischemic stroke or TIA (see section 4.5 and section 4.8).** 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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#### 4.8 Undesirable effects



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In TARDIS, patients with recent ischemic stroke receiving intensive antiplatelet therapy with three medicinal products (ASA + clopidogrel + dipyridamole) had more bleeding and bleeding of greater severity when compared with either clopidogrel alone or combined ASA and dipyridamole (adjusted common OR 2.54, 95% CI 2.05-3.16, P<0.00001).

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בעלון לצרכן:

2. לפני שימוש בתרופה

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תגובות בין תרופתיות:

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○ טיקלופידין-א תכשיריים אחרים נוגדי טסיות-אחר,

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העלונים המעודכנים נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלם מודפסים על ידי פנייה לבעל הרישום - סאנופי-אווונטיס ישראל בע"מ, רח' בני גאון 10 נתניה או בטלפון: 09-8633700.

להלן הקישור לאתר משרד הבריאות: <https://www.gov.il/he/service/israeli-drug-index>

בברכה,

חברת סאנופי-אווונטיס ישראל בע"מ