

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS'
REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed with a doctor's prescription only

Effient 5 mg

Coated tablets

Composition:

Each tablet contains:

Prasugrel (as Hydrochloride) 5 mg

Effient 10 mg

Coated tablets

Each tablet contains:

Prasugrel (as Hydrochloride) 10 mg

For the list of inactive ingredients and allergens, please see section "Additional information about the ingredients of this medicine" and section 6 "Additional information".

The medication contains lactose and may cause an allergy in people who are sensitive to lactose.

Read this leaflet carefully in its entirety before using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, please contact your doctor or pharmacist.

This medicine has been prescribed for the treatment of your illness. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

Effient is not intended for children and adolescents below 18 years of age, since there is no information about the efficacy and safety of this medicine in this age group.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Effient, co-administered with acetylsalicylic acid, is indicated for the prevention of atherothrombotic events in patients with acute coronary syndrome (unstable angina, acute myocardial infarction) who are undergoing initial or elective catheterization, with or without stent implantation.

Therapeutic group:

Platelet aggregation inhibitors.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients contained in this medicine (see section 6). An allergic reaction may appear as a rash, itching, swelling of the face and lips or shortness of breath.
- You suffer from active bleeding (such as bleeding from a peptic ulcer)
- You have ever had a stroke or a transient ischemic attack (TIA).
- You have severe liver disease.

Special warnings regarding the use of this medicine

During the course of treatment with this medicine, you must be under medical supervision.

Before starting treatment with Effient, tell your doctor if:

- You are over the age of 75 or weigh less than 60 kg. The risk of bleeding is higher for those patients. Therefore, should the doctor decide to treat such patients, a lower dose will be administered.
- You have suffered from a recent serious injury.
- You have undergone recent surgery (including some dental procedures).
- You have planned surgery (including some dental procedures), you must inform your doctor, as there may be a need to temporarily discontinue treatment due to an increased risk of bleeding.
- You have recent or recurrent bleeding from the stomach or intestines (including a stomach ulcer or colon polyps).
- You suffer from a renal (kidney) disease or moderate liver problems.
- You are taking additional medications (see the section "*Drug Interactions*").
- You have had an allergic reaction (hypersensitivity) to clopidogrel or any other anti-platelet agent. If you have taken **Effient** and experienced an allergic reaction that included rash, itching, a swollen face and tongue or shortness of breath - contact your doctor **immediately**.
- You experience a side effect called Thrombotic Thrombocytopenic Purpura (TTP), which includes fever and bruising under the skin that may appear as red pinpoint dots, with or without unexplained extreme tiredness, confusion, yellowing of the skin or eyes (jaundice) – contact the doctor immediately! (see section 4 – "*Side effects*").

Drug interactions:

If you are taking, or have taken recently, other medications including over-the-counter medicines and nutritional supplements, tell your doctor or pharmacist, especially inform your doctor or pharmacist if you are taking:

- Medications that may increase the risk of bleeding when given concomitantly with **Effient**:
 - Anti-platelet agents, such as clopidogrel
 - Anti-coagulants, such as warfarin and heparin
 - Non-steroidal anti-inflammatory drugs (NSAIDs, including COX-2 inhibitors), such as ibuprofen, naproxen, etoricoxib.
- Medications whose concentration in the blood is affected when used concomitantly with **Effient**:
 - Cyclophosphamide
 - Efavirenz
- A reduced efficacy in **Effient** treatment was observed in patients taking **Effient** and morphine concomitantly. Tell your doctor if you are taking morphine or other opioids (used to treat severe pain).

Taking Effient with food and drink:

Effient may be taken with or without food.

Pregnancy and breastfeeding:

If you are breastfeeding, pregnant or planning a pregnancy, you must consult your doctor regarding the possible risks to the fetus versus the benefit of taking this medication.

If you are breastfeeding, consult your doctor.

Driving and using machines:

Effient is unlikely to affect your ability to drive or use machines.

Important information about some of the ingredients of the medicine:

Effient contains lactose. If you have an intolerance to some sugars, contact your doctor before taking **Effient**.

3. HOW SHOULD YOU USE THIS MEDICINE?

- Always use this medicine as instructed by your doctor. You should check with your doctor or pharmacist if you are not sure about the dosage and manner of treatment with this medicine.
- The dosage and manner of treatment will be determined only by the doctor.
- **Do not exceed the recommended dose.**
- Take the tablet at around the same time every day.
- The tablet is coated. Do not chew, break or crush the tablet!
- You must be under medical supervision during treatment with this medication.
- **If you have accidentally taken a higher dose** or if a child has accidentally swallowed the medicine, proceed immediately to your doctor or hospital Emergency Room and bring the package of the medicine with you because you or your child are at an increased risk of bleeding.
- Do not induce vomiting without explicit instructions from the doctor!
- **If you forget to take this medicine at the scheduled time**, take a dose as soon as you remember. If you forgot to take the medicine for a whole day, take the next dose at the usual time the following day, but never take two doses on the same day!
- Treatment should be continued as recommended by the doctor.
- Even if there is an improvement in your health, do not stop taking this medicine without consulting your doctor or pharmacist. If you stop taking the medicine too soon, your risk of a heart attack may be higher.
- **Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.**
- **If you have any further questions about the use of this medicine, consult your doctor or pharmacist.**

4. SIDE EFFECTS

As with any medicine, the use of **Effient** may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

Contact a doctor as soon as possible if:

- You suffer from the following symptoms which may indicate a stroke:
You are suffering from sudden numbness or weakness of the arm, leg or face, especially if it happens only on one side of the body.

You experience sudden confusion, difficulty speaking or understanding others.
You experience a sudden difficulty in walking or loss of balance or coordination.
You experience a sudden dizziness or a sudden severe headache with no known cause.
If you have never had a stroke or transient ischemic attack (TIA), the probability of having a stroke as a side effect is low.

- You notice fever and bruising under the skin that may appear as red pinpoint dots - these symptoms may indicate Thrombotic Thrombocytopenic Purpura (TTP). This may be accompanied by unexplained extreme tiredness, confusion, and yellowing of the skin or eyes (jaundice) (see Section 2 - "*Before using this medicine*").
- You notice rash, itching, a swollen face and tongue or shortness of breath. These symptoms may be signs of a severe allergic reaction.
- You experience any of the following symptoms, which indicate bleeding:
 - You notice blood in your urine.
 - You are bleeding from the rectum, notice blood in your stools or your stool is black.
 - You experience uncontrollable bleeding, for example: bleeding from a cut or a wound. Bleeding is the most common side effect with **Effient**. Although uncommon, severe bleeding can be life-threatening.

Common side effects:

- Bleeding in the stomach or bowels.
- Bleeding from a needle puncture site.
- Nose bleeds.
- Skin rash.
- Bruising, particularly small red bruises on the skin (ecchymoses).
- Blood in urine.
- Hematoma (bleeding under the skin at the site of an injection, or into a muscle, causing swelling).
- Low hemoglobin or red blood cell count (anemia).

Uncommon side effects:

- An allergic reaction including angioedema (rash, itching, swollen lips/tongue, or shortness of breath).
- Spontaneous bleeding from the eye, rectum, gums or in the abdomen (around the internal organs).
- Bleeding after surgery.
- Coughing up blood.
- Blood in stools.

Rare side effects:

- Low blood platelet count
- Subcutaneous hematoma

If a side effects occurs, if one of the side effects gets worse, or if you suffer from a side effect not mentioned in this leaflet, you must consult a doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting Side Effects due to Drug Treatment" that can be found on the Home Page of the Ministry of Health's website (www.health.gov.il), which refers to the online form for reporting side effects, or via the following link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

5. HOW TO STORE THIS MEDICINE?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use this medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Do not store at a temperature above 30°C.
- Store in the original package in order to protect from air and moisture.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. ADDITIONAL INFORMATION

- In addition to the active ingredient, the medicine also contains:

Microcrystalline cellulose, Mannitol, Croscarmellose sodium, Hypromellose, Magnesium stearate, Lactose monohydrate, Titanium dioxide, Triacetin, Iron oxide yellow, Iron oxide red (only in the 10 mg tablet), Talc.

Each tablet contains no more than 0.68 mg sodium and 2.7 mg lactose.

- What the medicine looks like and contents of the pack:
Effient 5 mg is a yellow and double-arrow-shaped tablet, with "5 MG" debossed on one side and "4760" on the other.

Effient 10 mg is a beige and double-arrow shaped tablet, with "10 MG" debossed on one side and "4759" on the other.

The product comes in aluminium foil blisters containing 28 tablets.

Drug registration numbers:

Effient 5 mg: 142-55-32010-00

Effient 10 mg: 142-56-32011-00

Manufacturer: Lilly S.A., Alcobendas (Madrid), Spain

License holder: Eli Lilly Israel Ltd., P.O.Box 2160, Herzeliya Pituach 46120.

This leaflet has been reviewed and approved by the Ministry of Health in February 2014, and was updated according to the Ministry of Health guidelines in January 2019.

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