

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### **Efient 10 mg film-coated tablets** **Efient 5 mg film-coated tablets** Prasugrel

**Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Efient is and what it is used for
2. Before you take Efient
3. How to take Efient
4. Possible side effects
5. How to store Efient
6. Further information

#### **1. WHAT EFIENT IS AND WHAT IT IS USED FOR**

Efient belongs to a group of medicines called anti-platelet agents. Platelets are very small cell particles that circulate in the blood. When a blood vessel is damaged, for example if it is cut, platelets clump together to help form a blood clot (thrombus). Therefore, platelets are essential to help stop bleeding. If clots form within a hardened blood vessel such as an artery they can be very dangerous as they can cut off the blood supply, causing a heart attack (myocardial infarction), stroke or death. Clots in arteries supplying blood to the heart may also reduce the blood supply, causing unstable angina (a severe chest pain).

Efient inhibits the clumping of platelets and so reduces the chance of a blood clot forming.

You have been prescribed Efient because you have already had a heart attack or unstable angina and you have been treated with a procedure to open blocked arteries in the heart. You may also have had one or more stents placed to keep open a blocked or narrowed artery supplying blood to the heart. Efient reduces the chances of you having a further heart attack or stroke or of dying from one of these atherothrombotic events. Your doctor will also give you acetylsalicylic acid (e.g. aspirin), another anti-platelet agent.

#### **2. BEFORE YOU TAKE EFIENT**

##### **Do not take Efient**

- If you are allergic (hypersensitive) to prasugrel or any of the other ingredients of Efient. An allergic reaction may be recognised as a rash, itching, a swollen face, swollen lips or shortness of breath. If this has happened to you, tell your doctor **immediately**.
- If you have a medical condition that is currently causing bleeding, such as bleeding from your stomach or intestines.
- If you have ever had a stroke or a transient ischaemic attack (TIA).
- If you have severe liver disease.

### **Take special care with Efient**

You should tell your doctor before taking Efient if any of the situations mentioned below apply to you:

- If you have an increased risk of bleeding such as:
  - age of 75 years or older. Your doctor should prescribe a daily dose of 5 mg as there is a greater risk of bleeding in patients older than 75 years
  - a recent serious injury
  - recent surgery (including some dental procedures)
  - recent or recurrent bleeding from the stomach or intestines (e.g. a stomach ulcer or colon polyps)
  - body weight of less than 60 kg. Your doctor should prescribe a daily dose of 5 mg of Efient if you weigh less than 60 kg
  - renal (kidney) disease or moderate liver problems
  - taking certain types of medicines (see 'Taking other medicines' below)- planned surgery (including some dental procedures) in the next seven days. Your doctor may wish you to stop taking Efient temporarily due to the increased risk of bleeding
- If you are Asian - there is limited experience of Efient use in Asians
- If you have had allergic reactions (hypersensitivity) to clopidogrel or any other anti-platelet agent please tell your doctor before starting treatment with Efient. If you then take Efient and experience allergic reactions that may be recognised as a rash, itching, a swollen face, swollen lips or shortness of breath you need to tell your doctor **immediately**.

While you are taking Efient:

You should tell your doctor **immediately** if you develop a medical condition called Thrombotic Thrombocytopenic Purpura (or TTP) that 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) (see section 4 'POSSIBLE SIDE EFFECTS').

### **Taking other medicines**

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, dietary supplements and herbal remedies. It is particularly important to tell your doctor if you are being treated with clopidogrel (an anti-platelet agent), warfarin (an anti-coagulant), or "non steroidal anti inflammatory drugs" for pain and fever (such as ibuprofen, naproxen, etoricoxib). If given together with Efient these medicines may increase the risk of bleeding

Only take other medicines while you are on Efient if your doctor tells you that you can.

### **Taking Efient with food and drink**

Efient may be taken with or without food.

### **Pregnancy and breast-feeding**

Tell your doctor if you become pregnant or are trying to become pregnant while you are taking Efient. You should use Efient only after discussing with your doctor the potential benefits and any potential risks to your unborn child.

If you are breast-feeding, ask your doctor or pharmacist for advice before taking any medicine.

### **Driving and using machines**

No studies on the effects of Efient on the ability to drive and use machines have been performed. Efient is unlikely to affect your ability to drive or use machines.

### **Important information about some of the ingredients of Efient**

Efient contains lactose. If you have been told by a doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

### 3. HOW TO TAKE EFIENT

Always take Efient exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how many Efient tablets to take. The usual dose of Efient is 10 mg per day. You will start the treatment with a single dose of 60 mg.

If you weigh less than 60 kg or are more than 75 years of age, the dose is 5 mg Efient per day. Your doctor will also tell you to take acetylsalicylic acid- (s)he will tell you the exact dose to take (usually between 75 mg and 325 mg daily).

You may take Efient with or without food. Take your dose at around the same time every day. Do not break or crush the tablet.

It is important that you tell your doctor, dentist and pharmacist, that you are taking Efient. Efient should not be used in children and adolescents below 18 years of age.

#### **If you take more Efient than you should**

Contact your doctor or hospital straight away, as you may be at risk of excessive bleeding. You should show the doctor your pack of Efient.

#### **If you forget to take Efient**

If you miss your scheduled daily dose, take Efient when you remember. If you forget your dose for an entire day, just resume taking Efient at its usual dose the next day. Do not take two doses in one day. For the 14, 28, 56 84 and 98 tablet pack sizes, you can check the day on which you last took a tablet of Efient by referring to the calendar printed on the blister.

#### **If you stop taking Efient**

Do not stop taking Efient without consulting your doctor. It is especially important to discuss with your doctor before stopping Efient because both the risks and the benefits are based on regular use.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### 4. POSSIBLE SIDE EFFECTS

Like all medicines, Efient can cause side effects, although not everybody gets them.

Contact your doctor **immediately** if you notice any of the following:

- Sudden numbness or weakness of the arm, leg or face, especially if only on one side of the body
- sudden confusion, difficulty speaking or understanding others
- sudden difficulty in walking or loss of balance or co-ordination
- sudden dizziness or sudden severe headache with no known cause

All of the above may be signs of a stroke. Stroke is an uncommon side effect of Efient in patients who have never had a stroke or transient ischaemic attack (TIA).

Also contact your doctor **immediately** if you notice any of the following:

- 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). (see section 2 'BEFORE YOU TAKE EFIENT')
- A rash, itching, or a swollen face, swollen lips/tongue, or shortness of breath. These may be signs of an allergic reaction (see section 2 'BEFORE YOU TAKE EFIENT')

Tell your doctor **promptly** if you notice any of the following:

- Blood in your urine
- Bleeding from your rectum, blood in your stools or black stools
- Uncontrollable bleeding, for example from a cut

All of the above may be signs of bleeding, the most common side effect with Efient. Although uncommon, severe bleeding can be life-threatening.

*Common side effects (affect 1 to 10 users in 100)*

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

*Uncommon side effects (affect 1 to 10 users in 1,000)*

- Allergic reaction (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 (affect 1 to 10 users in 10,000)*

- Low blood platelet count
- Subcutaneous haematoma (bleeding under the skin causing a swelling)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell you doctor or pharmacist.

## **5. HOW TO STORE EFIENT**

Keep out of the reach and sight of children.

Do not use Efient after the expiry date, which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month.

Store in the original package to protect from air and moisture.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## **6. FURTHER INFORMATION**

### **What Efient contains**

- The active substance is prasugrel.  
Efient 10 mg: Each tablet contains 10 mg of prasugrel (as hydrochloride).  
Efient 5 mg: Each tablet contains 5 mg of prasugrel (as hydrochloride).

- The other ingredients are microcrystalline cellulose, mannitol (E421), croscarmellose sodium, hypromellose (E464) magnesium stearate, lactose monohydrate, titanium dioxide (E171), triacetin (E1518), iron oxide red (10 mg tablets only) (E172), iron oxide yellow (E172) and talc.

### **What Efient looks like and contents of the pack**

Efient 10 mg: The tablets are beige and double-arrow shaped, with "10 MG" debossed on one side and "4759" on the other.

Efient 5 mg: The tablets are yellow and double-arrow-shaped, with "5 MG" debossed on one side and "4760" on the other.

Efient is available in packs of 14, 28, 30, 56, 84, 90 and 98 tablets.  
Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

Eli Lilly Nederland BV  
Grootslag 1 – 5  
NL-3991 RA, Houten  
The Netherlands.

### **Manufacturer:**

Lilly S.A.  
Avda. de la Industria 30  
28108 Alcobendas  
Madrid  
Spain.

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

### **Belgique/België/Belgien**

Daiichi Sankyo Belgium N.V.-S.A  
Tél/Tel: +32 (0) 10 48 95 95

### **България**

ТП "Ели Лили Недерланд" Б.В. - България  
тел. +359 2 491 41 40

### **Česká republika**

ELI LILLY ČR, s.r.o.  
Tel: +420 234 664 111

### **Danmark**

Eli Lilly Danmark A/S  
Tlf: +45 45 26 60 00

### **Deutschland**

Daiichi Sankyo Deutschland GmbH  
Tel. +49 (0) 69 50 98 53 41

### **Eesti**

Eli Lilly Holdings Limited Eesti filiaal  
Tel: +372 6 817 280

### **Ελλάδα**

ΦΑΡΜΑΣΕΡΒ-ΛΙΛΛΥ Α.Ε.Β.Ε.  
Τηλ: +30 210 629 4600

### **España**

Daiichi Sankyo España, S.A.  
Tel: +34 (0) 91 539 99 11

### **Luxembourg/Luxemburg**

Daiichi Sankyo Belgium N.V.-S.A  
Tél/Tel: +32 (0) 10 48 95 95

### **Magyarország**

Lilly Hungária Kft.  
Tel: + 36 1 328 5100

### **Malta**

Charles de Giorgio Ltd.  
Tel: +356 25600 500

### **Nederland**

Daiichi Sankyo Nederland B.V.  
Tel: +31 (0) 20 4 07 20 72

### **Norge**

Eli Lilly Norge A.S.  
Tlf: +47 22 88 18 00

### **Österreich**

Daiichi Sankyo Austria GmbH  
Tel: +43 (0) 1 481 06 45

### **Polska**

Eli Lilly Polska Sp. z o.o.  
Tel. +48 (0) 22 440 33 00

### **Portugal**

Daiichi Sankyo Portugal, Lda.  
Tel: +351 21 4232010

**France**

Daiichi Sankyo France SAS

Tél: +33 (0) 1 55 62 14 60

**Ireland**

Daiichi Sankyo UK Ltd

Tel: +44 (0) 1753 893 600

**Ísland**

Icepharma hf.

Sími: +354 540 8000

**Italia**

Daiichi Sankyo Italia S.p.A.

Tel: +39 (0) 06 85 2551

**Κύπρος**

Phadisco Ltd

Τηλ: +357 22 715000

**Latvija**

Eli Lilly Holdings Limited pārstāvniecība Latvijā

Tel: +371 67364000

**Lietuva**

Eli Lilly Holdings Limited atstovybė

Tel. +370 (5) 2649600

**România**

Eli Lilly România S.R.L.

Tel: +40 21 4023000

**Slovenija**

Eli Lilly farmacevtska družba, d.o.o.

Tel: +386 (0)1 580 00 10

**Slovenská republika**

Eli Lilly Slovakia, s.r.o.

Tel: +421 220 663 111

**Suomi/Finland**

Oy Eli Lilly Finland Ab

Puh/Tel: +358-(0) 9 85 45 250

**Sverige**

Eli Lilly Sweden AB

Tel: + 46 (0) 8 7378800

**United Kingdom**

Daiichi Sankyo UK Ltd

Tel: +44 (0) 1753 893 600

**This leaflet was last approved in {MM/YYYY}.**

Detailed information on this medicine is available on the European Medicines Agency web site:  
<http://www.ema.europa.eu>