

EFFIENT[®] FILM COATED TABLETS

Prasugrel (5 dan 10mg)

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What Effient is used for

Effient is a prescription medicine used to treat people who:

- have had a heart attack or severe chest pain that happens when your heart does not get enough oxygen, and
- have been treated with a procedure to open a blocked artery in the heart, with or without a stent (small mesh tube) being placed in the artery

Effient is used to lower your chance of having another serious problem with your heart or blood vessels, such as another heart attack, a stroke, blood clots in your stent, or death.

How Effient works

Effient, which contains the active substance prasugrel, belongs to a group of medicines called antiplatelet agents. Platelets are blood cells that help with normal blood clotting. Effient helps prevent platelets from sticking together and forming a clot that can block an artery or a stent.

Before you use Effient

- When you must not use it

Do not take Effient

- If you are allergic (hypersensitive) to prasugrel or any of the other ingredients of Effient. An allergic reaction may be recognized 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 has a stroke or a transient ischaemic attack (TIA, also known as “mini-stroke”, where stroke symptoms [see section **Side effects**] happen suddenly and disappear within 24 hours).
- If you have severe liver disease.

- Before you start to use it

Effient may not be right for you. Tell your doctor about all of your medical conditions, including if you:

- have any bleeding problems
- have has a stroke or TIA
- are allergic to any medicines, including clopidogrel (Plavix*) or ticlopidine hydrochloride (Ticlid*)
- have a history of stomach ulcers, colon polyps (abnormal growth of tissue found in colon), diverticulosis (a condition where abnormal pouches form in the colon)
- have liver problems
- have kidney problems
- have had any recent severe injury or surgery
- plan to have surgery especially a type of heart surgery called Coronary Artery Bypass Graft (CABG) or dental procedure

- are pregnant or are planning to get pregnant while you are taking Effient. You should use Effient only after discussing with your doctor the potential benefits and any potential risks to your unborn child. It is not known if Effient will harm your baby
- if you are breast-feeding, ask your doctor or pharmacist for advice before taking any medicine. It is not known if Effient passes into your breast-milk. You and your doctor should decide if you will take Effient or breast-feed. You should not do both without talking with your doctor.
- are 75 years or older as there is a greater risk of bleeding in patients older than 75 years.
- weigh less than 60 kg. Your doctor should prescribe a daily dose of 5 mg of Effient if you weigh less than 60 kg

- 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 blood thinning agents (such as clopidogrel, heparin and warfarin), or “non steroidal anti inflammatory drugs (NSAID)” for pain and fever (such as ibuprofen, naproxen, and etoricoxib). If given together with Effient these medicine may increase the risk of bleeding

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

How to use Effient

- How much to use

Always take Effient 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 Effient tablets to take. The usual dose of Effient is 10 mg orally once daily. You will start the treatment with a single dose of 60 mg.

If you weigh less than 60 kg the dose is 5 mg Effient per day.

Your doctor will also tell you to take acetylsalicylic acid (also known as aspirin) - (s)he will tell you the exact dose to take (usually between 75 mg and 325 mg daily).

Effient should not be used in children and adolescents below 18 years of age.

- When to use it

Use as directed by your doctor or pharmacist.

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

- How long to use it

Continue taking Effient for as long as your doctor recommends.

- If your forget to use it

If you miss your scheduled daily dose, take Effient when you remember. If you forget your dose for an entire day, just resume taking Effient at its usual

dose the next day. Do not take two doses in one day.

- If you use too much (overdose)

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

While you are using it

- Things you must do

Before you have any surgery, or start taking any new medicines, it is important that you tell your doctor, dentist and pharmacist, that you are taking Effient.

You should tell your doctor immediately if you develop a medical condition called Thrombotic Thrombocytopenic Purpura (or TTP, a blood clotting problem where blood clots form in blood vessels and can happen all over the body. Symptoms see section **Side effects**).

- Things you must not do

Do not stop taking Effient without consulting your doctor. It is especially important to discuss with your doctor before stopping Effient 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.

- Things to be careful of

Effient increases your risk of bleeding (See side effect) because it lessens the ability of your blood to clot.

While you take Effient:

- you will bruise and bleed more easily
- you are more likely to have nose bleeds
- it will take longer for any

bleeding to stop

Side effects

Like all medicines, Effient 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 of 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 Effient in patients who have never had a stroke or TIA.

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).

All of the above may be signs of TTP. TTP can occur after a brief exposure to Effient (less than 2 weeks)

Also tell your doctor

immediately if you notice any of the following:

- A rash, itching
- A swollen face, swollen lips/tongue
- Shortness of breath

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These may be signs of an allergic reaction to Effient.

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
- Uncontrolled bleeding, for example from a cut

All of the above may be signs of bleeding, the most common side effect with Effient. Although uncommon, severe bleeding can be life-threatening. Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of Effient. For more information, ask your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

Storage and Disposal of Effient

- Storage

Keep out of the reach and sight of children.

Store below 30°C. Store in the original package to protect from air and moisture.

- Disposal

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

Product Description

- What it looks like

Effient 10 mg: the tablets are beige and double-arrow shaped, with “10 MG” debossed on one side and “4759” on the other.

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

- Ingredients

- Active ingredient

Effient 10 mg: Each tablet contains 10 mg of prasugrel (as hydrochloride).

Effient 5 mg: Each tablet contains 5 mg of prasugrel (as hydrochloride).

- Inactive ingredients

The other ingredients are microcrystalline cellulose, mannitol (E421), croscarmellose sodium, hypromellose (E464), magnesium stearate, colour mixture Yellow (for Effient 5mg only), colour mixture beige (for Effient 10mg only) and talc.

- MAL number(s):

Effient 10mg (MAL20102003A)

Effient 5mg (MAL20102002A)

Manufacturer

Eli Lilly and Company
Lilly Technology Center,
Indianapolis,
Indiana, 46221, USA

Product Registration Holder

Eli Lilly Malaysia Sdn Bhd
Level 7, Menara OBYU,
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