Package Leaflet: Information for the user

Efient® 5mg film-coated tablets

(prasugrel)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Efient 5mg film-coated tablets but will be referred to as Efient throughout this leaflet. Please note that this leaflet also contains information about other strength Efient 10mg film-coated tablets.

What is in this leaflet

1. What Efient is and what it is used for
2. What you need to know before you take Efient
3. How to take Efient
4. Possible side effects
5. How to store Efient
6. Contents of the pack and other information

1. What Efient is and what it is used for

Efient, which contains the active substance prasugrel, 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. What you need to know before you take Efient

Do not take Efient
- If you are allergic to prasugrel or any of the other ingredients of this medicine (listed in section 6). 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.

Warnings and precautions

- **Before you are taking Efient:**

Talk to your doctor before taking 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 5mg 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 60kg. Your doctor should prescribe a daily dose of 5mg of Efient if you weigh less than 60kg
  - renal (kidney) disease or moderate liver problems
  - taking certain types of medicines (see 'Other medicines and Efient' 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 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 Thrombocytopaenic 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').

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

Other medicines and Efient
Tell your doctor if you are taking, have recently taken or might take 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),
- '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.

Tell your doctor if you are taking morphine or other opioids (used to treat severe pain).

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

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 pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
Efient is unlikely to affect your ability to drive or use machines.

Efient contains lactose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. This medicine contains less than 1mmol sodium (23mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Efient

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose of Efient is 10mg per day. You will start the treatment with a single dose of 60mg. If you weigh less than 60kg or are more than 75 years of age, the dose is 5mg 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 75mg and 325mg 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.

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 a double dose to make up for a forgotten dose. 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; if you stop taking Efient too soon, your risk of a heart attack may be higher.

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

4. Possible side effects

Like all medicines, this medicine 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 'What you need to know before you take Efient').
- A rash, itching, or a swollen face, swollen lips/tongue, or shortness of breath. These may be signs of a severe allergic reaction (see section 2 'What you need to know 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 (may affect up to 1 in 10 people)
- 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 (may affect up to 1 in 100 people)
- 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 (may affect up to 1 in 1,000 people)
- Low blood platelet count
- Subcutaneous haematoma (bleeding under the skin causing a swelling)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:
www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store.**
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Efient
Keep out of the sight and reach of children.
Store in the original package in order to protect from air and moisture.
Do not take the tablets after the expiry date, which is stated on the carton and blister labels after 'Exp'. The expiry date refers to the last day of that month.
If the tablet becomes discoloured or shows any signs of deterioration, seek the advice of your pharmacist.
Remember if your doctor tells you to stop taking this medicine, return any unused medicine to your pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.
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. Contents of the pack and other information

What Efient contains
The active ingredient in the Efient is prasugrel.
Each tablet contains 5mg 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 yellow (E172) and talc.

What Efient looks like and contents of the pack
Efient is yellow and double-arrow-shaped, with '5 MG' debossed on one side and '4760' on the other.

It is available in pack size of 28 tablets.

Manufactured by: Vetprom AD, The Vpharma site, 26 Otets Paisiy Str., Radomir, 2400, Bulgaria.
OR
Daiichi Sankyo Europe GmbH, Luitpoldstrasse 1, 85276 Pfaffenhofen, Germany.
Procured from within the EU & repackaged by the Product Licence holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

Efient® 5mg film-coated tablets; PL 18799/4128

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Leaflet date: 19.08.2026

For any information about this medicine, please contact the Product Licence Holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.
Tel: 0800 049 9401
Email: regulatorygroup@bnshealthcare.com

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Blind or partially sighted?
Is this leaflet hard to see or read?
Call **0208 515 3763** to obtain the leaflet in a format suitable for you.

Package Leaflet: Information for the user

Prasugrel 5mg film-coated tablets

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- Keep this leaflet. You may need to read it again.
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- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Prasugrel 5mg film-coated tablets but will be referred to as Prasugrel throughout this leaflet. Please note that this leaflet also contains information about other strength Prasugrel 10mg film-coated tablets.

What is in this leaflet

1. What Prasugrel is and what it is used for
2. What you need to know before you take Prasugrel
3. How to take Prasugrel
4. Possible side effects
5. How to store Prasugrel
6. Contents of the pack and other information

1. What Prasugrel is and what it is used for

Prasugrel, which contains the active substance prasugrel, 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).

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

You have been prescribed Prasugrel 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. Prasugrel 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. What you need to know before you take Prasugrel

Do not take Prasugrel
- If you are allergic to prasugrel or any of the other ingredients of this medicine (listed in section 6). 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.

Warnings and precautions

- **Before you are taking Prasugrel:**

Talk to your doctor before taking Prasugrel.

You should tell your doctor before taking Prasugrel 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 5mg 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 60kg. Your doctor should prescribe a daily dose of 5mg of Prasugrel if you weigh less than 60kg
  - renal (kidney) disease or moderate liver problems
  - taking certain types of medicines (see 'Other medicines and Prasugrel' below)
  - planned surgery (including some dental procedures) in the next seven days. Your doctor may wish you to stop taking Prasugrel temporarily due to the increased risk of bleeding
- If you have had allergic reactions (hypersensitivity) to clopidogrel or any other anti-platelet agent, please tell your doctor before starting treatment with Prasugrel. If you then take Prasugrel 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 Prasugrel:**

You should tell your doctor immediately if you develop a medical condition called Thrombotic Thrombocytopaenic 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').

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

Other medicines and Prasugrel
Tell your doctor if you are taking, have recently taken or might take 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),
- 'non steroidal anti-inflammatory drugs' for pain and fever (such as ibuprofen, naproxen, etoricoxib).

If given together with Prasugrel these medicines may increase the risk of bleeding.

Tell your doctor if you are taking morphine or other opioids (used to treat severe pain).

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

Pregnancy and breast-feeding
Tell your doctor if you become pregnant or are trying to become pregnant while you are taking Prasugrel. You should use Prasugrel only after discussing with your doctor the potential benefits and any potential risks to your unborn child.
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
Prasugrel is unlikely to affect your ability to drive or use machines.

Prasugrel contains lactose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. This medicine contains less than 1mmol sodium (23mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Prasugrel

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose of Prasugrel is 10mg per day. You will start the treatment with a single dose of 60mg. If you weigh less than 60kg or are more than 75 years of age, the dose is 5mg Prasugrel per day. Your doctor will also tell you to take acetylsalicylic acid- (s)he will tell you the exact dose to take (usually between 75mg and 325mg daily).

You may take Prasugrel 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 Prasugrel.

If you take more Prasugrel 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 Prasugrel.

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

If you stop taking Prasugrel
Do not stop taking Prasugrel without consulting your doctor; if you stop taking Prasugrel too soon, your risk of a heart attack may be higher.

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

4. Possible side effects

Like all medicines, this medicine 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 Prasugrel 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 'What you need to know before you take Prasugrel').
- A rash, itching, or a swollen face, swollen lips/tongue, or shortness of breath. These may be signs of a severe allergic reaction (see section 2 'What you need to know before you take Prasugrel').

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 Prasugrel. Although uncommon, severe bleeding can be life-threatening.

Common side effects (may affect up to 1 in 10 people)
- 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 (may affect up to 1 in 100 people)
- 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 (may affect up to 1 in 1,000 people)
- Low blood platelet count
- Subcutaneous haematoma (bleeding under the skin causing a swelling)

Reporting of side effects
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www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store.**
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Prasugrel

Keep out of the sight and reach of children.
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Remember if your doctor tells you to stop taking this medicine, return any unused medicine to your pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.
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. Contents of the pack and other information

What Prasugrel contains
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The other ingredients are:
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What Prasugrel looks like and contents of the pack
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It is available in pack size of 28 tablets.

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Prasugrel 5mg film-coated tablets; PL 18799/4128

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Leaflet date: 19.08.2026

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