

Product Name	Prasugrel		Colours Used
PIP Code	UK 676-5770-01	■	Black
Old PIP Code	UK 675-8817-PIL	■	Keyline
Variation No.	Seq. 0025 - In line with ref.		
Customer	Sovereign Medical		
Market	UK		
Language	English		
Size	150 x 320 mm (PIL)		
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Approved for submission

Pharmacode

UK 676-5770-01

Package leaflet: Information for the user
**Prasugrel Waymade 5 mg film-coated tablets
Prasugrel Waymade 10 mg film-coated tablets**

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.

What is in this leaflet

1. What Prasugrel film-coated tablets are and what they are used for
2. What you need to know before you take Prasugrel film-coated tablets
3. How to take Prasugrel film-coated tablets
4. Possible side effects
5. How to store Prasugrel film-coated tablets
6. Contents of the pack and other information

1. What Prasugrel film-coated tablets are and what they are used for

The name of your medicine is Prasugrel Waymade 5 mg and 10 mg film-coated Tablets (referred to as Prasugrel film-coated tablets in this leaflet).

Prasugrel film-coated tablets, which contain the active substance prasugrel, belong 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 film-coated tablets inhibit the clumping of platelets and so reduce the chance of a blood clot forming.

You have been prescribed Prasugrel film-coated tablets 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 film-coated tablets reduce 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 film-coated tablets
Do not take Prasugrel film-coated tablets

- If you are allergic to prasugrel or any of the other ingredients of Prasugrel film-coated tablets. 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 had a stroke or a transient ischaemic attack (TIA).
- If you have severe liver disease.

Warnings and precautions
Before you are taking Prasugrel film-coated tablets:

Talk to your doctor before taking Prasugrel film-coated tablets.

You should tell your doctor before taking Prasugrel film-coated tablets 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 Prasugrel film-coated tablets if you weigh less than 60 kg
 - renal (kidney) disease or moderate liver problems
 - taking certain types of medicines (see 'Other medicines and Prasugrel film-coated tablets' below)
 - planned surgery (including some dental procedures) in the next seven days. Your doctor may wish you to stop taking Prasugrel film-coated tablets 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 film-coated tablets. If you then take Prasugrel film-coated tablets and experience allergic reactions that may be recognized 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 film-coated tablets:

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').

Children and adolescents

Prasugrel film-coated tablets should not be used in children and adolescents below 18 years of age.

Other medicines and Prasugrel film-coated tablets

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), or "non-steroidal anti-inflammatory drugs" for pain and fever (such as ibuprofen, naproxen, etoricoxib). If given together with Prasugrel film-coated tablets 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 film-coated tablets 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 film-coated tablets. You should use Prasugrel film-coated tablets 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 film-coated tablets are unlikely to affect your ability to drive or use machines.

Prasugrel film-coated tablets contain lactose and sodium.

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

3. How to take Prasugrel film-coated tablets

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

Dose

The usual dose of Prasugrel film-coated tablets 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 Prasugrel film-coated tablets 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).

Administration

You may take Prasugrel film-coated tablets with or without food. Take your dose at around the same time every day. Do not break or crush the tablet.

The tablet blister strip may contain a large round silica tablet, used to protect the tablets from moisture. See Section 5 'How to store Prasugrel film-coated tablets'. DO NOT remove the large round tablet from the blister strip. DO NOT eat the silica tablet.

It is important that you tell your doctor, dentist and pharmacist, that you are taking Prasugrel film-coated tablets.

If you take more Prasugrel film-coated tablets 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 film-coated tablets.

If you forget to take Prasugrel film-coated tablets

If you miss your scheduled daily dose, take Prasugrel film-coated tablets when you remember. If you forget your dose for an entire day, just resume taking Prasugrel film-coated tablets at its usual

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dose the next day. Do not take a double dose to make up for a forgotten dose. You can check the day on which you last took a tablet by referring to the days of the week printed on each tablet blister strip.

If you stop taking Prasugrel film-coated tablets

Do not stop taking Prasugrel film-coated tablets without consulting your doctor; if you stop taking Prasugrel film-coated tablets 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 film-coated tablets 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 film-coated tablets').
- 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 film-coated tablets').

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 film-coated tablets. 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, pharmacist or nurse. 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 Prasugrel film-coated tablets

Keep this medicine out of the sight and reach of children.

Do not use this medicine 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.

Tablet blister strips of 14 tablets (without a silica tablet):
Do not store above 30°C.

Tablet blister strips of 7 tablets (containing a large round silica tablet):

This medicinal product does not require any special storage conditions. Once the first tablet has been removed from a blister strip the remaining tablets in that strip should be taken within 7 days. Do not remove the silica tablet from the blister pack. Do not eat the silica tablet.

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 protect the environment.

6. Contents of the pack and other information

What Prasugrel film-coated tablets contains

- The active substance is prasugrel.
Each Prasugrel 5 mg film-coated tablet contains 5 mg of prasugrel.
Each Prasugrel 10 mg film-coated tablet contains 10 mg of prasugrel.

- The other ingredients are:

- Tablet Core:
Docusate Sodium, Hydroxypropylcellulose, Mannitol, Microcrystalline cellulose, Croscarmellose sodium, Magnesium stearate.

- Film-Coat (5 mg):

Opadry II Yellow 31K520003 (which contains: Lactose monohydrate, Hypromellose (E464), Titanium dioxide (E171), Triacetin, Iron oxide yellow (E172)).

- Film-Coat (10 mg):

Opadry II Brown 31K565001 (which contains: Hypromellose (E464), Lactose monohydrate, Triacetin, Iron oxide yellow (E172), Titanium dioxide (E171), Iron oxide red (E172), Iron oxide black (E172)).

What Prasugrel film-coated tablets look like and contents of the pack

Prasugrel 5 mg film-coated tablets: Yellow coloured, capsule-shaped, film-coated tablet, debossed with 'L651' on one side and plain on the other side. Tablet dimensions – length approximately 8 mm and width approximately 5 mm.

Prasugrel 10 mg film-coated tablets: Brown coloured, capsule-shaped, film-coated tablet, debossed with 'L452' on one side and plain on the other side. Tablet dimensions – length approximately 11 mm and width approximately 5 mm.

Prasugrel film-coated tablets are available in calendar blister packs of 28 film-coated tablets in blister strips of 4 x 7 tablets (each blister strip contains a large round silica tablet in the centre), and blister strips of 2 x 14 tablets (without a silica tablet).

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Sovereign Medical,
Sovereign House,
Miles Gray Road, Basildon,
Essex, SS14 3FR, UK

Manufacturer

Waymade Plc,
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PL 06464/3099 Prasugrel Waymade 5 mg film-coated tablets
PL 06464/3100 Prasugrel Waymade 10 mg film-coated tablets

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