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PACKAGE LEAFLET: INFORMATION FOR THE USER

Prasugrel 5mg Film-Coated Tablets Prasugrel 10mg 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.

What is in this leaflet

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

1. What Prasugrel tablets are and what they are used for

Prasugrel tablets, which contain 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.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Prasugrel tablets

Do not take Prasugrel tablets

- If you are allergic (hypersensitive) to prasugrel or any of the other ingredients of Prasugrel tablets. 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 tablets

Talk to your doctor before taking Prasugrel tablets

You should tell your doctor before taking Prasugrel 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 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 tablets if you weigh less than 60kg
- 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 Prasugrel 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 tablets. If you then take Prasugrel tablets 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 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 tablets should not be used in children and adolescents below 18 years of age.

Other medicines and Prasugrel 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 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 tablets if your doctor tells you that you can.

Prasugrel tablets with food and drink

You may take Prasugrel with or without food.

Pregnancy, breast-feeding and fertility

Pregnancy

Tell your doctor if you become pregnant or are trying to become pregnant while you are taking Prasugrel tablets.

You should use Prasugrel tablets only after discussing with your doctor the potential benefits and any potential risks to your unborn child.

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

Breast-feeding

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

Driving and using machines

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

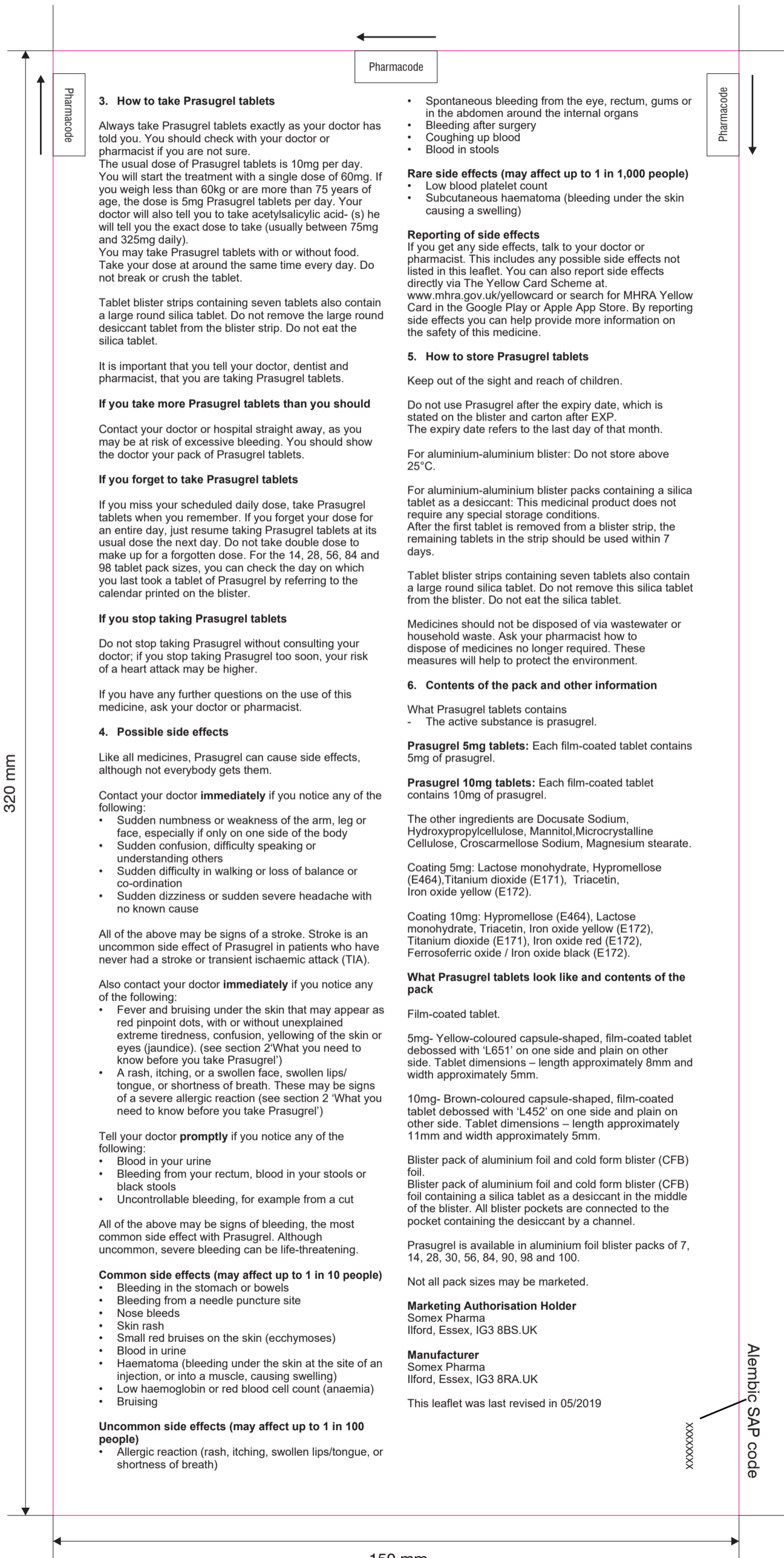
Prasugrel contains lactose monohydrate

If you have been told by a doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

320 mm

150 mm
Front Side

Type: Packinsert
Size : 150 x 320 mm (L x W)



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3. How to take Prasugrel tablets

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

The usual dose of Prasugrel tablets 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 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 75mg and 325mg daily).

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

Tablet blister strips containing seven tablets also contain a large round silica tablet. Do not remove the large round desiccant 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 tablets.

If you take more Prasugrel 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 tablets.

If you forget to take Prasugrel tablets

If you miss your scheduled daily dose, take Prasugrel tablets when you remember. If you forget your dose for an entire day, just resume taking Prasugrel tablets at its usual dose the next day. Do not take 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 tablets

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, Prasugrel 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

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 Prasugrel tablets

Keep out of the sight and reach of children.

Do not use Prasugrel 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.

For aluminium-aluminium blister: Do not store above 25°C.

For aluminium-aluminium blister packs containing a silica tablet as a desiccant: This medicinal product does not require any special storage conditions.

After the first tablet is removed from a blister strip, the remaining tablets in the strip should be used within 7 days.

Tablet blister strips containing seven tablets also contain a large round silica tablet. Do not remove this silica tablet from the blister. Do not eat the silica tablet.

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 tablets contains

- The active substance is prasugrel.

Prasugrel 5mg tablets: Each film-coated tablet contains 5mg of prasugrel.

Prasugrel 10mg tablets: Each film-coated tablet contains 10mg of prasugrel.

The other ingredients are Docusate Sodium, Hydroxypropylcellulose, Mannitol, Microcrystalline Cellulose, Croscarmellose Sodium, Magnesium stearate.

Coating 5mg: Lactose monohydrate, Hypromellose (E464), Titanium dioxide (E171), Triacetin, Iron oxide yellow (E172).

Coating 10mg: Hypromellose (E464), Lactose monohydrate, Triacetin, Iron oxide yellow (E172), Titanium dioxide (E171), Iron oxide red (E172), Ferrosoferric oxide / Iron oxide black (E172).

What Prasugrel tablets look like and contents of the pack

Film-coated tablet.

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

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

Blister pack of aluminium foil and cold form blister (CFB) foil.

Blister pack of aluminium foil and cold form blister (CFB) foil containing a silica tablet as a desiccant in the middle of the blister. All blister pockets are connected to the pocket containing the desiccant by a channel.

Prasugrel is available in aluminium foil blister packs of 7, 14, 28, 30, 56, 84, 90, 98 and 100.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Somex Pharma
Ilford, Essex, IG3 8BS.UK

Manufacturer

Somex Pharma
Ilford, Essex, IG3 8RA.UK

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Alembic SAP code

150 mm
Back Side

Type: Packinsert
Size : 150 x 320 mm (L x W)