Package leaflet: Information for the user

Prasugrel Mylan 5 mg film-coated tablets
Prasugrel Mylan 10 mg 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 Mylan is and what it is used for
2. What you need to know before you take Prasugrel Mylan
3. How to take Prasugrel Mylan
4. Possible side effects
5. How to store Prasugrel Mylan
6. Contents of the pack and other information

1. What Prasugrel Mylan is and what it is used for

Prasugrel Mylan, which contains the active substance prasugrel, belongs to a group of medicines called antiplatelet 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 Mylan inhibits the clumping of platelets and so reduces the chance of a blood clot forming.

You have been prescribed Prasugrel Mylan 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 Mylan 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 antiplatelet agent.

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

Do not take Prasugrel Mylan 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.
- have a medical condition that is currently causing bleeding, such as bleeding from your stomach or intestines.

have ever had a stroke or a transient ischaemic attack (TIA).
- have severe liver disease.

Warnings and precautions

Before you take Prasugrel Mylan:

Talk to your doctor before taking Prasugrel Mylan.

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

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

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

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

Tell your doctor if you become pregnant or are trying to become pregnant while you are taking Prasugrel Mylan. You should use Prasugrel Mylan 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
Prasugrel Mylan is unlikely to affect your ability to drive or use machines.

Prasugrel Mylan 5 mg contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

Prasugrel Mylan 10 mg contains sunset yellow FCF aluminium lake (E110) and sodium
Sunset yellow FCF aluminium lake is a colouring agent, which may cause allergic reactions.
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Prasugrel Mylan

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 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 Mylan per day. Your doctor will also tell you to take acetylsalicylic acid, and (s)he will tell you the exact dose to take (usually between 75 mg and 325 mg daily).

You may take Prasugrel Mylan 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 Mylan.

If you take more Prasugrel Mylan 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 Mylan.

If you forget to take Prasugrel Mylan
If you miss your scheduled daily dose, take Prasugrel Mylan when you remember. If you forget your dose for an entire day, just resume taking Prasugrel Mylan at its usual dose the next day. Do not take a double dose to make up for a forgotten dose.

If you stop taking Prasugrel Mylan
Do not stop taking Prasugrel Mylan without consulting your doctor; if you stop taking Prasugrel Mylan 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 Mylan 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 Mylan')
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 Mylan')

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 Mylan. 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 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. You can also report side effects directly via YellowCard Scheme Website: 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 Mylan

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 bottle and carton after EXP. The expiry date refers to the last day of that month.

Prasugrel Mylan 5 mg: Do not store above 30°C. Store in the original package in order to protect from moisture.

Prasugrel Mylan 10 mg: Do not store above 25°C. Store in the original package in order to protect from moisture.
Blister packs only: Do not store above 30°C. Store in the original package in order to protect from moisture.

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 to protect the environment.

6. Contents of the pack and other information

What Prasugrel Mylan contains
The active substance is prasugrel.
Prasugrel Mylan 5 mg: Each film-coated tablet contains prasugrel besilate equivalent to 5 mg prasugrel.
Prasugrel Mylan 10 mg: Each film-coated tablet contains prasugrel besilate equivalent to 10 mg prasugrel.

The other ingredients are:
Prasugrel Mylan 5 mg: microcrystalline cellulose, mannitol, crospovidone, silica colloidal anhydrous, magnesium stearate, polyvinyl alcohol, talc, titanium dioxide (E171), glyceryl monocaprylocaprate, sodium lauryl sulfate, iron oxide yellow (E172). See section 2 ‘Prasugrel Mylan 5 mg contains sodium’.

Prasugrel Mylan 10 mg: microcrystalline cellulose, mannitol, crospovidone, silica colloidal anhydrous, magnesium stearate, polyvinyl alcohol, talc, titanium dioxide (E171), glyceryl monocaprylocaprate, sodium lauryl sulfate, iron oxide yellow (E172), sunset yellow FCF aluminium lake (E110), iron oxide red (E172). See section 2 ‘Prasugrel Mylan 10 mg contains sunset yellow FCF aluminium lake and sodium’.

What Prasugrel Mylan looks like and contents of the pack

Prasugrel Mylan 10 mg film-coated tablets are beige film-coated, capsule shaped, biconvex tablets, of dimensions 11.15 mm × 5.15 mm, debossed with ‘PH4’ on one side of the tablet and ‘M’ on the other side.
This medicine is available in plastic bottles containing a desiccant and 28 or 30 film-coated tablets and in blister packs containing 28, 30, 84, 90, 98 and in perforated blister packs containing 30 x 1 and 90 x 1 film-coated tablets.

Prasugrel Mylan 5 mg film-coated tablets are yellow film-coated, capsule shaped, biconvex tablets, of dimensions 8.15 mm × 4.15 mm, debossed with ‘PH3’ on one side of the tablet and ‘M’ on the other side.
This medicine is available in plastic bottles containing a desiccant and 28 or 30 film-coated tablets and in blister packs containing 28, 30, 84 or 98 film-coated tablets.

Do not eat or remove the desiccant contained in the bottle

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Mylan Pharmaceuticals Limited, Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland

Manufacturer
Mylan Hungary Kft
Mylan utca 1, Komárom, 2900, Hungary

McDermott Laboratories Limited t/a Gerard Laboratories
35/36 Baldoyle Industrial Estate, Grange State, Dublin 13, Ireland

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

United Kingdom (Northern Ireland)
Mylan IRE Healthcare Limited
Tel: +353 18711600

This leaflet was last revised in March 2023

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