

Prasugrel Lupin

Consumer Medicine Information (CMI) Summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Prasugrel Lupin?

Prasugrel Lupin contains the active ingredient prasugrel. Prasugrel Lupin is used to prevent blood cells from clotting.

For more information, see Section [1. Why am I using Prasugrel Lupin?](#) in the full CMI.

2. What should I know before I use Prasugrel Lupin?

Do not use if you have ever had an allergic reaction to prasugrel or any of the ingredients listed at the end of the CMI.

Talk to your doctor or pharmacist if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Prasugrel Lupin?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Prasugrel Lupin and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Prasugrel Lupin?

- Take Prasugrel Lupin as directed by your doctor or pharmacist. This may differ from the information contained in this leaflet.

More instructions can be found in Section [4. How do I use Prasugrel Lupin?](#) in the full CMI.

5. What should I know while using Prasugrel Lupin?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Prasugrel Lupin. • If you or you are going to have surgery, tell the surgeon that you are taking this medicine. • If you or you are about to have any blood tests, tell your doctor that you are taking this medicine. • If you become pregnant while taking this medicine, tell your doctor immediately.
Things you should not do	• Do not stop taking Prasugrel Lupin or change the dosage without checking with your doctor. • Do not take Prasugrel Lupin to treat any other complaints unless prescribed by your doctor. • Do not give your medicine to anyone else, even if they have the same condition as you
Driving or using machines	• Be careful driving or operating machinery until you know how it affects you.
Looking after your medicine	• Keep your tablets in a cool dry place where the temperature stays below 25°C

For more information, see Section [5. What should I know while using Prasugrel Lupin?](#) in the full CMI.

6. Are there any side effects?

Some common side effects with Prasugrel Lupin include: rash; nose bleeds; cuts taking longer than usual to stop bleeding; bleeding gums. Serious side effects include: signs of anemia; uncontrollable bleeding; coughing up blood; pink or brown urine; blood in the eyes.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Prasugrel Lupin

Active ingredient(s): prasugrel (as hydrochloride)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Prasugrel Lupin. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Prasugrel Lupin.**

Where to find information in this leaflet:

- [1. Why am I using Prasugrel Lupin?](#)
- [2. What should I know before I use Prasugrel Lupin?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Prasugrel Lupin?](#)
- [5. What should I know while using Prasugrel Lupin?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Prasugrel Lupin?

Prasugrel Lupin contains the active ingredient prasugrel. Prasugrel belongs to the group of medicines called antiplatelet agents.

Prasugrel Lupin is used to prevent blood cells from clotting. It is used by people who have had a PCI (percutaneous coronary intervention) because of unstable angina or a heart attack.

PCI is a procedure where a balloon-tipped tube is used to open a blocked artery, with or without a stent being placed in the artery.

It works by reducing the ability of blood cells to clot. By preventing blood cells from clumping, it reduces the chances of blood clots forming (a process called thrombosis), thereby decreasing or even stopping blood supply to the heart muscle.

Prasugrel Lupin is always taken with aspirin.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another use. If you want more information, ask your doctor..

2. What should I know before I use Prasugrel Lupin?

Warnings

Do not use Prasugrel Lupin if:

- you are allergic to prasugrel, or any of the ingredients listed at the end of this leaflet.
Always check the ingredients to make sure you can use this medicine.

Symptoms of an allergic reaction may include:

- shortness of breath;
 - wheezing or difficulty breathing;
 - swelling of the face, lips, tongue or other parts of the body;
 - rash;
 - itching.
- you have had any of the following medical conditions:
 - bleeding caused by a stomach ulcer;
 - bleeding inside your head;
 - stroke;
 - transient ischaemic attack (TIA) which resulted in a temporary paralysis, numbness, speech difficulty or other symptoms affecting your nervous system which happened suddenly and disappeared within 24 hours;
 - severe liver disease.
 - the packaging is torn or shows signs of tampering (or the tablets do not look quite right).
 - the expiry date on the pack has passed. If you take this medicine after the expiry date has passed, it may not work as well.

Do not give this medicine to children. There is no experience with the use of this medicine in children.

Check with your doctor if you:

- are not sure if you have an allergy to prasugrel.
- take any medicines for any other condition.
- have any allergies to any other medicines including those you have previously taken to prevent your blood from clotting, or any other substances such as foods, preservatives or dyes.
- are already taking aspirin.
- have, or have had, any of the following medical conditions:
 - bleeding disorders or blood clotting problems;
 - a tendency to bleed as a result of a recent trauma, recent surgery (including dental surgery), recent or recurrent gastrointestinal bleeding, active peptic ulcer disease;
 - a history of kidney or liver problems;
 - a history of stroke or TIA;
 - weigh less than 60 kg;
 - are more than 75 years old;
 - a history of tumours or cancer.
- are planning to have surgery (including dental procedures).

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Prasugrel Lupin.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Your doctor will discuss the possible risks and benefits of taking this medicine during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Prasugrel Lupin is not recommended while you are breastfeeding. It is not known whether it passes into breast milk.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

You will be prescribed aspirin at a low dose with Prasugrel Lupin. Aspirin works together with Prasugrel Lupin.

Some medicines may interfere with Prasugrel Lupin and affect how it works.

These include:

- medicines that “thin the blood” such as warfarin and heparin. There are others so please check with your doctor or pharmacist.
- non-steroidal anti-inflammatory drugs (NSAIDs) – medicines used to treat arthritis, period pain, aches and pain.
- fibrinolytics – a group of medicines used to dissolve a blood clot that has formed in an artery or a vein.
- some medicines used to treat HIV (eg. efavirenz).
- some medicines used to treat cancer (eg. cyclophosphamide).
- morphine or other opioids, medicines to treat pain.

These medicines may be affected by Prasugrel Lupin or may affect how well it works. You may need different amounts of your medicine or you may need to take different medicines.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines. They also have a more complete list of medicines to be careful with or avoid while taking Prasugrel Lupin.

These may differ from the information contained in this leaflet.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Prasugrel Lupin.

4. How do I use Prasugrel Lupin?

How much to take

- Your doctor will tell you how many tablets to take each day.

- Prasugrel Lupin is available as a 5 mg and 10 mg tablet. It is usual for your doctor to start you on a single dose of six 10 mg tablets and then continue with a 10 mg or 5 mg once daily dose.
- Your doctor will also prescribe a daily dose of aspirin to take with this medicine.

When to take Prasugrel Lupin

- **Take your Prasugrel Lupin tablets at the same time each day.** Taking your tablets at the same time will have the best effect. It will also help you to remember when to take it.
- The tablets can be taken before or after meals.
- **Continue taking Prasugrel Lupin for as long as your doctor recommends.**

How to take Prasugrel Lupin

- You should swallow the tablets with a glass of water.
- **Do not break the tablet in half. Talk to your doctor or pharmacist if you have trouble swallowing tablets.**

If you forget to use Prasugrel Lupin

Prasugrel Lupin should be used regularly at the same time each day.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much Prasugrel Lupin

If you think that you have used too much Prasugrel Lupin, you may need urgent medical attention.

You should immediately:

- telephone the National Poisons Centre (0800 POISON or 0800 764 766),; or
- contact your doctor; or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Prasugrel Lupin?

Things you should do

- **Take Prasugrel Lupin every day exactly as your doctor has prescribed.**
- **If you become pregnant while you are taking it, tell your doctor.**
- **If you decide to breastfeed your baby, tell your doctor.** Your doctor may want to discuss this and change your medicine.
- **Tell your doctor, dentist or pharmacist that you are taking Prasugrel Lupin before you have any surgery.** It may increase the risk of bleeding during an operation or some dental work. Therefore, treatment may need to be stopped before surgery. Your doctor

will decide whether to stop Prasugrel Lupin and if so, for how long.

- **Ask your doctor whether there are any activities you should avoid while taking this medicine, for example, certain sports.** Sometimes after an injury, bleeding may occur inside your body without you knowing about it.

Call your doctor straight away if you:

- **are injured while taking this medicine.** It may take longer than usual to stop bleeding while you are taking Prasugrel Lupin.
- **notice the return of any of the symptoms you had before starting Prasugrel Lupin.**

Remind any doctor, dentist or pharmacist you visit that you are using Prasugrel Lupin.

Things you should not do

- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not stop taking this medicine without informing your doctor as it may increase the chance of a heart attack or stroke or a blood clot forming.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Prasugrel Lupin affects you.

Make sure you know how you react to it before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy or light-headed. If this does occur, do not drive.

Drinking alcohol

Tell your doctor if you drink alcohol.

If you drink alcohol, faintness or dizziness may be worse.

Looking after your medicine

- Store Prasugrel Lupin tablets below 25°C.
- Keep your tablets in the blister pack until it is time to take them.

Follow the instructions on the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink; or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• Rash. • Nose bleeds. • Cuts that take longer than usual to stop bleeding. • Bleeding gums.	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
• Signs of anaemia (being tired and looking pale). • Severe or uncontrollable bleeding, including after surgery. • Coughing up blood (a sign of bleeding from the stomach). • Pink or brown urine. • Red or black stools. • Diarrhoea with blood, mucus, stomach pain and fever (a sign of bleeding from the intestine). • Unusual bruising (bruises that develop without known cause or grow in size). • Red or purple spots visible through your skin. • Unusually heavy bleeding or bruising from cuts or wounds. • Blood in the eyes. • Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to Medsafe online at <https://pophealth.my.site.com/carmreportnz/s/>.

By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor’s prescription.

What Prasugrel Lupin contains

Active ingredient (main ingredient)	Prasugrel
Other ingredients (inactive ingredients)	Croscarmellose sodium Microcrystalline cellulose Lactose monohydrate Crospovidone Sucrose stearate Opadry II 32K220036 Yellow (5 mg) Opadry II 32K230012 Orange (10 mg)
Potential allergens	Lactose and sugars

Do not take this medicine if you are allergic to any of these ingredients.

What Prasugrel Lupin looks like

Prasugrel Lupin 5 mg tablets are yellow, oblong-shaped, biconvex, film-coated tablets debossed on one side with “F1” and plain on the other side.

Prasugrel Lupin 10 mg tablets are orange, oblong-shaped, biconvex, film-coated tablets debossed on one side with “F2” and plain on the other side.

Who distributes Prasugrel Lupin

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