

**PREDONIUM 2/0.625
PREDONIUM DS 4/1.25**

perindopril (pronounced per-in-do-pril) and indapamide (pronounced ind-ap-a-mide)

What is in this leaflet

The name of your medicine is PREDONIUM or PREDONIUM DS. PREDONIUM DS is a ‘double strength’ of PREDONIUM. All of the information below applies to both medicines, so to make this leaflet easier to read only the name PREDONIUM is used.

This leaflet answers some common questions about PREDONIUM. It does not contain all the available information about this medicine. Reading this leaflet does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking PREDONIUM against the expected benefits for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What PREDONIUM and PREDONIUM DS are

PREDONIUM contains the active ingredients perindopril erbumine and indapamide hemihydrate. Perindopril belongs to a group of medicines called angiotensin converting enzyme (ACE) inhibitors. Indapamide belongs to a group of medicines called chlorosulphamoyl diuretics.

What PREDONIUM is used for

You have been prescribed PREDONIUM for high blood pressure.

PREDONIUM is available only with a doctor’s prescription.

There is no evidence that PREDONIUM is addictive.

Why PREDONIUM is used for high blood pressure

Everyone has blood pressure. This pressure helps to circulate blood all around the body. Your blood pressure may be different at different times of the day, depending on how busy or stressed you are. You have high blood pressure (also known as hypertension) when your blood pressure stays higher than is needed, even when you are calm and relaxed.

If high blood pressure is not treated it can lead to serious health problems. You may feel fine and have no symptoms, but eventually it can cause stroke, heart disease and kidney failure.

PREDONIUM helps to lower your blood pressure.

Ask your doctor if you have any questions about why PREDONIUM has been prescribed for you.

Before you take PREDONIUM

There are some people who should not take PREDONIUM. Please read the lists below. If you think any of these situations apply to you, or you have any questions, please consult your doctor or pharmacist.

Do not take PREDONIUM if:

- You are allergic to perindopril, indapamide, or any of the other ingredients of PREDONIUM listed at the end of this leaflet.
- You are allergic to sulphonamide (sulpha) antibiotics, or to thiazide diuretics (a type of “fluid” or “water” tablet).

- You are pregnant or trying to become pregnant.
- You are breastfeeding or plan to breast-feed.
- You undergo renal dialysis using polyacrylonitrile membranes.
- You have renal artery stenosis (a problem with the blood vessels to one or both kidneys).
- You have experienced serious swelling of the face, tongue, lips or throat either suddenly or in response to another medicine in the past (a rare allergic condition known as angio-oedema).
- The packaging is torn or shows signs of tampering, or the tablets do not look quite right.
- The expiry date (EXP) on the pack has passed.

Tell your doctor straight away if:

- You become pregnant while you are taking PREDONIUM.
- You are undergoing desensitisation treatment, or have had an allergic reaction during previous desensitisation treatment (e.g. treatments using bee, wasp or ant venom).
- You are undergoing, or have had an allergic reaction during previous low-density lipoprotein (LDL) apheresis, a technique where LDL is ‘filtered’ out of a patient’s blood, using dextran sulphate.
- You have any other health problems, including:
 - Kidney disease.
 - Liver disease.
 - High or low levels of potassium, sodium, or other problems with salt balance.
 - Diabetes.
 - Gout.
 - Heart disease.
 - Systemic lupus erythematosus (a disease affecting the skin, joints and kidneys).

Taking other medicines

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

Taking PREDONIUM may change the effect of some medicines, and some medicines may affect how well PREDONIUM works. You may need different amounts of your medication or to take different medicines. The medicines that may interact with PREDONIUM include the following:

- Some anaesthetic drugs.
- Some drugs used to treat gout (allopurinol).
- Some steroid medicines.
- Some drugs used to treat cancer or to suppress the immune system.
- Diuretics (sometimes called “fluid” or “water” tablets).
- Lithium medications (used to treat mood swings and some types of depression).
- Sources of potassium, like potassium tablet and salt substitutes containing potassium.
- Some medications used to treat high blood pressure, a fast or irregular heartbeat, and other heart conditions.
- Medicines used to treat diabetes (tablets and insulin).

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking PREDONIUM.

For older people or children

- Elderly people can generally use PREDONIUM safely. However, some older people have reduced kidney function – in which case additional care may be required.
- **PREDONIUM is not recommended for use in children.**

How to take PREDONIUM

Follow all directions given to you by your doctor and pharmacist carefully. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Your doctor will select a dose when they prescribe PREDONIUM for you. The usual dose is one tablet once daily.

Swallow your tablet(s) with a glass of water, preferably in the morning.

How long to take PREDONIUM for

PREDONIUM can help to control your blood pressure but cannot cure this condition. PREDONIUM treatment is usually for life – so you should keep taking the tablets regularly unless advised otherwise by your doctor.

If you forget to take PREDONIUM

- If your next usual dose is less than 6 hours away, just leave out the dose that you missed. Take the next dose at the usual time and continue as normal.
- If your next dose is more than 6 hours away, take the dose you have missed as soon as you realise. Then take the next dose at the usual time and continue as normal.

Do not try to make up for missed doses by taking more than one dose at a time.

If you take too much PREDONIUM

Taking too much PREDONIUM (an overdose) may cause low blood pressure (also known as hypotension). Other effects like sickness, cramps, sleepiness, confusion, kidney problems, salt and water disturbances are possible. You may require urgent medical attention.

If you think that you or anyone else may have taken too much PREDONIUM then act immediately:

- Telephone your doctor or the Poisons Information Centre (13 11 26 in Australia; 0800 764 766 in New Zealand), or go to the Accident and Emergency department at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

While you are taking PREDONIUM

Things you must do

Take PREDONIUM exactly as your doctor has prescribed. Otherwise you may not get the benefits from treatment.

Tell all doctors, dentists and pharmacists who are involved with your treatment that you are taking PREDONIUM.

Make sure you drink enough water during exercise and hot weather especially if you sweat a lot. This will help you avoid any dizziness or light-headedness caused by a sudden drop in blood pressure.

Tell your doctor straight away if you have excessive vomiting or diarrhoea while taking PREDONIUM.

Things you must not do

Do not give this medicine to anyone else, even they have the same condition as you.

Do not use PREDONIUM to treat any other complaints unless your doctor tells you to.

Do not stop taking PREDONIUM or change the dose, without checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how PREDONIUM affects you.

You may feel light-headed or dizzy when you begin to take PREDONIUM. This is because your blood pressure is falling. If you have these symptoms when standing up or getting out of bed then getting up more slowly can help. This allows your body to get used to the change in position and blood pressure. If you have these symptoms and they don't get better in a short time then talk to your doctor.

Side effects

If you do not feel well while you are taking PREDONIUM then tell your doctor or pharmacist as soon as possible.

All medicines can have side effects. Most of the time they are not serious but sometimes they can be.

PREDONIUM helps most people with high blood pressure, but it may sometimes have unwanted side effects. These can include:

- A dry cough.
- Headache.

- Feeling tired or as if you have less energy.
- Feeling faint, light-headed, or dizzy.
- Feeling sick or having stomach pain.
- Muscle pain.
- An increased risk of becoming dehydrated (in elderly patients and in patients with heart failure).
- Low potassium levels. Symptoms of low potassium can include a number of those listed above, and very occasionally this may be severe.

Most of these side effects are mild when they occur. Do not be alarmed by this list of possible side effects. You may not experience any of them. However, if you do – or if you notice anything else that is making you feel unwell - you should consult your doctor or pharmacist.

If any of the signs below occur then tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital:

- Swelling of your lips, face, mouth, tongue or throat.
- Purple spots with occasional blisters on the front of your arms and legs and/or around your neck and ears (A rare condition known as Stevens-Johnson Syndrome).
- A fast and irregular heart beat.
- Severe blisters, skin rash, itching or other allergic reactions.

These side effects are extremely rare but can become serious.

After taking PREDONIUM

Storage

Keep your PREDONIUM tablets where children cannot reach them. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines. **Keep your tablets in the pack until it is time to take them. PREDONIUM will not keep as well outside its blister packaging.**

Heat and dampness can destroy some medicines. Keep them in a cool, dry place where the temperature stays below 30°C. Do not store medicines in a bathroom or near a sink. Do not leave them in a car or on a windowsill.

Disposal

If your doctor tells you to stop taking PREDONIUM, or the tablets have passed their expiry date, return any leftover tablets to your pharmacist for disposal.

What PREDONIUM looks like

White rod-shaped tablets supplied in a blister pack of 30 tablets.

PREDONIUM tablets are scored, while PREDONIUM DS tablets are not.

The blister strip of PREDONIUM tablets comes in a foil sachet (with a desiccant), while the PREDONIUM DS blister strip does not.

Ingredients

Each tablet of PREDONIUM contains 2mg of perindopril erbumine and 0.625mg of indapamide hemihydrate as active ingredients.

Each tablet of PREDONIUM DS contains 4mg of perindopril erbumine and 1.25mg of indapamide hemihydrate as active ingredients.

The inactive ingredients in PREDONIUM and PREDONIUM DS tablets include cellulose - microcrystalline, lactose, magnesium stearate, and silica - colloidal anhydrous.

The tablets are gluten free.

Manufacturer

PREDONIUM is a product discovered by Servier Research International.

The New Zealand contact address for Servier Laboratories is:
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Auckland

This leaflet was last revised in March 2006