

PREXUM[®] COMBI LD 2.5/0.625; PREXUM[®] COMBI 5/1.25

perindopril (pronounced per-in-do-priil) and indapamide (pronounced in-dap-a-mide)

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about PREXUM COMBI. 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 PREXUM COMBI 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 PREXUM COMBI IS

The name of your medicine is PREXUM COMBI. The medicine contains the active ingredients perindopril arginine and indapamide hemihydrate. Perindopril belongs to a group of medicines called angiotensin converting enzyme (ACE) inhibitors. Indapamide belongs to a group of medicines called diuretics (a type of "water" tablet).

WHAT PREXUM COMBI IS USED FOR

You have been prescribed PREXUM COMBI for high blood pressure.

PREXUM COMBI is available only with a doctor's prescription.

There is no evidence that PREXUM COMBI is addictive.

Why PREXUM COMBI 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.

PREXUM COMBI helps to lower your blood pressure.

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

BEFORE YOU TAKE PREXUM COMBI

There are some people who should not take PREXUM COMBI. 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 PREXUM COMBI if:

- **You are allergic to perindopril, indapamide, or any of the other ingredients of PREXUM COMBI 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 allergic to another angiotensin converting enzyme (ACE) inhibitor.**
- **You are pregnant or trying to become pregnant.**
- **You are breastfeeding or plan to breast-feed.**
- **You undergo treatments where your blood is treated outside of the body (also known as extracorporeal treatments) that may increase your risk of allergic reactions, treatments such as:**
 - renal dialysis or haemofiltration using

polyacrylonitrile membranes

- low-density lipoprotein (LDL) apheresis, a technique where LDL is 'filtered' out of a patient's blood, using dextran sulphate.
- You are treated with a blood pressure lowering medicine containing aliskiren and have diabetes or impaired kidney function.
- You have kidney problems where the blood supply to your kidneys is reduced (renal artery stenosis).
- You are suffering from decreases in the amount, or absence of, urine produced by the kidney.
- You have narrowing of the main blood vessel leading from the heart and/or heart valve.
- If you have low blood potassium.
- If you have severe liver disease or suffer from a condition called hepatic encephalopathy (degenerative disease of the brain that occurs as a result of liver disease).
- 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 angioedema).
- You are treated with sacubitril/valsartan a medicine used to treat long-term heart failure (see also 'Tell Your Doctor Straight Away' and 'Taking Other Medicines' sections).
- The packaging is damaged 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 are pregnant or become pregnant while taking PREXUM COMBI, as it may cause serious harm to your unborn baby.
 - You have a severe allergic reaction with swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (angioedema). This may occur at any time during treatment. If you develop such symptoms, you should stop taking PREXUM COMBI and see a doctor immediately (see also 'SIDE EFFECTS' section).
 - 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 you are intending to undergo, treatments where your blood is treated outside of the body (also known as extracorporeal treatments).
 - You are undergoing anaesthesia and/or surgery.
 - You are undergoing a medical test that requires injection of an iodinated contrast agent (a substance that makes organs like the kidney or stomach visible on an X-ray)
 - You have recently suffered from diarrhoea or vomiting, or are dehydrated.
 - You are on a salt restricted diet or use salt substitutes which contain potassium.
 - You have an intolerance to some sugars as PREXUM COMBI contains lactose.
 - You are of African origin since you may have a higher risk of angioedema and this medicine is less effective in lowering your blood pressure.
 - You are taking lithium (used to treat mania or depression).
- You are taking any of the following medicines used to treat high blood pressure:
 - an 'angiotensin II receptor blocker' (also known as ARBs or sartans - for example valsartan, telmisartan, irbesartan), in particular if you have diabetes-related kidney problems
 - sacubitril (available as fixed-dose combination with another medicine valsartan), used to treat long-term heart failure
 - aliskiren.
 - You have any other health problems, including:
 - Kidney disease or if you are on renal dialysis
 - Liver disease
 - High or low levels of potassium, sodium, or other problems with salt balance
 - Diabetes
 - Gout
 - Heart disease
 - Hardening of the arteries
 - Hyperparathyroidism (overactive parathyroid gland)
 - Photosensitivity reactions (increased sensitivity of the skin to sun)
 - Systemic lupus erythematosus or scleroderma (a disease affecting the skin, joints and kidneys)
 - Abnormally increased levels of a hormone called aldosterone in your blood (primary aldosteronism)
 - If you experience a decrease in vision or eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye or an increase of pressure in your eye and can happen within hours to a week of taking PREXUM COMBI. This can lead to permanent vision loss, if not treated. If you earlier have had

a penicillin or sulfonamide allergy, you can be at higher risk of developing this.

- muscle disorders including muscle pain, tenderness, weakness or cramps.

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

- Some steroid medicines
- Diuretics (sometimes called 'fluid' or 'water' tablets because they increase the amount of urine passed each day, e.g. amiloride, spironolactone, triamterene)
- Medicines used for heart rhythm problems (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, flecainide)
- Some medications used to treat high blood pressure (including angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blockers), aliskiren (see also 'Do Not Take PREXUM COMBI If' and 'Tell Your Doctor Straight Away' sections)
- Some treatments where your blood is treated outside of the body, also known as extracorporeal treatments (see also 'Do Not Take PREXUM COMBI If' and 'Tell Your Doctor Straight Away' sections)
- Some antibiotic and medicines used to treat infections (e.g. trimethoprim, moxifloxacin)
- Medicines used to treat fungal disease (e.g. Amphotericin B by injection, fluconazole)
- Tetracosactide (to treat Crohn's disease)
- Some anti-inflammatory medicines (including high dose aspirin, ibuprofen) for pain relief
- Some anaesthetic medicines.
- Medicines used to treat mental illnesses such as some medicines for epilepsy, anxiety, schizophrenia and some other antidepressants (e.g. lithium, tricyclic antidepressants, antipsychotics drugs, neuroleptics such as: droperidol, haloperidol, chlorpromazine, trifluoperazine, amisulpride, sulphiride, psychoanaleptics).
- Antiparasitic medicines used to treat certain types of malaria (e.g. chloroquine).
- Pentamidine (a medicine used to treat certain types of pneumonia).
- Antihistamines used to treat allergic reactions, such as hay fever.
- Medicines used to treat nausea and vomiting (e.g. ondansetron, domperidone).
- Medicines used to treat gastrointestinal problems (e.g. cisapride, papaverine).
- Potassium-sparing diuretics (e.g. spironolactone, triamterene), sources of potassium, like potassium tablet and salt substitutes containing potassium, other drugs which can increase potassium in your body (such as heparin and co-trimoxazole also known as trimethoprim/sulfamethoxazole)
- Medicines used to treat cancer (e.g. vandetanib, oxaliplatin) or to suppress the immune system (e.g. cyclosporin, tacrolimus).
- Non-steroidal anti-inflammatory drugs for pain relief (e.g. ibuprofen) or high doses of aspirin.
- Vasodilators including nitrates
- Medicines used to treat diabetes (e.g. metformin, gliptins and insulin)
- Baclofen (a medicine used to treat muscle stiffness in diseases such as multiple sclerosis)
- Medicines used for the treatment of low blood pressure, shock or asthma (e.g. ephedrine, noradrenaline or adrenaline)
- Gold salts, especially with intravenous administration (used to treat symptoms of rheumatoid arthritis)
- Medicines which may affect the blood cells, such as allopurinol, procainamide
- Medicines which may increase the risk of angioedema (a severe allergic reaction) such as
 - Mammalian target of rapamycin (mTOR) inhibitors used to avoid rejection of transplanted organs (e.g. temsirolimus, sirolimus, everolimus)
 - Sacubitril (available as fixed-dose combination with valsartan), used to treat long-term heart failure (see also 'Do Not Take PREXUM COMBI If' and 'Tell Your Doctor Straight Away' sections).
- Iodinated contrast agent used in certain medical tests
- Methadone (a medicine used to treat severe pain or opioid addiction)
- Digoxin or other cardiac glycosides (for the treatment of heart problems)
- Calcium supplements
- Stimulant laxatives (e.g. senna).
- Medicines used to treat bacterial infections (e.g. moxifloxacin, ciprofloxacin, clarithromycin)
- Allopurinol (a medicine used to treat gout).
- Cilostazol (used to treat cramp-like pain in the legs when you walk).

Your doctor or pharmacist has more information on medicines to be

careful with or avoid while taking PREXUM COMBI.

For older people or children

Elderly people can generally use PREXUM COMBI safely. However, some older people have reduced kidney function - in which case additional care may be required.

PREXUM COMBI is not recommended for use in children and adolescents.

HOW TO TAKE PREXUM COMBI

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 PREXUM COMBI for you. The usual dose is one tablet once daily.

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

How long to take PREXUM COMBI for

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

If you forget to take PREXUM COMBI

- 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 PREXUM COMBI

Taking too much PREXUM COMBI (an overdose) may cause low blood pressure (also known as hypotension).

The most likely effect in case of overdose is low blood pressure which can make you feel dizzy. If this happens, lying down with the legs elevated can help.

Other effects like, nausea, vomiting, cramps, sleepiness, confusion changes in the amount of urine produced by the kidney are possible. You may require urgent medical attention.

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

Telephone your doctor or the Poisons Information Centre (13 11 26 in Australia; 03 474 7000 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 PREXUM COMBI

Things you must do

Take PREXUM COMBI 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 PREXUM COMBI.

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 PREXUM COMBI

Things you must not do

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

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

Do not stop taking PREXUM COMBI 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 PREXUM COMBI affects you.

You may feel light-headed or dizzy when you begin to take PREXUM COMBI. 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 PREXUM COMBI then tell your doctor or pharmacist as soon as possible.

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

PREXUM COMBI helps most people with high blood pressure, but it may sometimes have unwanted side effects in a few people. While these side effects when they occur are usually mild they can be serious.

Stop taking PREXUM COMBI and see a doctor immediately, if you experience any of the following side effects that can be serious:

- Dizziness becoming severe or fainting induced by low blood pressure
- Difficulty breathing or wheezing, tightening of the chest. (Uncommon)
- Angioedema (a severe allergic reaction) has been reported in patients treated with ACE inhibitors, including PREXUM COMBI. This may occur at any time during treatment. If you develop such symptoms described below you should tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital. These side effects are extremely rare but can become serious. Swelling of your extremities (limbs, hands or feet), lips, face, mouth, tongue or throat. (Uncommon)
- 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). (Very rare)
- Painful red areas, developing large blisters and peeling of layers of skin. This is accompanied by fever and chills (a condition known as Toxic Epidermal Necrolysis or TEN). (Very rare)
- Red, often itchy spots, similar to the rash of measles, which starts on the limbs and sometimes on the face and the rest of the body (a condition known as Erythema Multiforme). (Very rare)
- Stroke (signs include weakness of arms or legs or problems speaking). (Very rare)
- Heart disorders such as a fast and irregular heart beat, heart attack, angina pectoris (a feeling of tightness, pressure or heaviness in the chest). (Very rare)

- Inflammation of the pancreas (Pancreatitis). (Very rare)
- Liver disease (Hepatitis) characterised by yellowing of the skin or eyes (jaundice). (Very rare)
- Life-threatening irregular heart beat (Torsades de pointes). (Frequency not known)
- Disease of the brain caused by liver illness (Hepatic encephalopathy) (Frequency not known).
- Muscle spasms, tenderness, pain or weakness and particularly, if at the same time, you feel unwell or have a high temperature it may be caused by an abnormal muscle breakdown (frequency not known).

The above side effects are categorised into the following frequencies:

Common - may affect up to 1 in 10 people

Uncommon - may affect up to 1 in 100 people

Rare - may affect up to 1 in 1,000 people

Very rare - may affect up to 1 in 10,000 people

Not known - frequency cannot be estimated from the data available

Talk to your doctor or pharmacist or nurse if you notice any of the following side effects, some of which are usually only identified after blood tests:

Common (may affect up to 1 in 10 people) side effects can include:

- Cough, often described as dry and irritating, shortness of breath, discomfort on exertion
- Nosebleeds
- Headache, dizziness, vertigo, pins and needles
- Feeling tired or weak
- Tinnitus (persistent noise in the ears), vertigo, vision impairment

- Low blood pressure (and related effects), flushing, impaired peripheral circulation, vasculitis
- Nausea, vomiting, taste disturbances, indigestion, diarrhoea, constipation, stomach pain or discomfort
- Dry mouth
- Decreased appetite
- Muscle spasms
- Muscle tenderness or weakness
- Rash, pruritus (itching), red raised skin rash
- Hypersensitivity reactions, mainly skin reactions, in patients with allergies and asthmatic reactions.

Uncommon (may affect up to 1 in 100 people) side effects can include:

- High levels in the blood of potassium, urea and/or creatine
- Low sodium (salt) levels in the blood
- Altered mood, sleep disorder (difficulty sleeping, abnormal dreams), feeling sleepy or drowsy, fainting.
- Anxiety
- Bronchitis, upper respiratory tract infection
- Back pain
- Gastrointestinal inflammation
- Excessive sweating.
- Increased sensitivity of the skin to sun, skin rash or inflammation of the skin often including blisters that weep and become crusted
- Pemphigoid - a skin disease usually affecting older people
- Increase in some white blood cells
- Erectile dysfunction, libido disorder
- Fever or high temperature
- Chest pain
- Fast heart beat
- Palpitations (awareness of your heartbeat)

- Abnormal ECG heart tracing
- Abnormal kidney function
- Polyuria - increased urination
- Cystitis - an infection of the bladder
- Decreased blood sugar levels
- Worsening of pre-existing Lupus Erythematosus
- Aching muscles, not caused by exercise, Joint pain
- Generally feeling unwell or lethargic
- Falls
- Vasculitis (inflammation of blood cells)
- Impaired peripheral circulation
- Syncope - fainting not associated with seizures or trauma.

Rare (may affect up to 1 in 1,000 people) side effects can include:

- Elevation of bilirubin levels in the blood, increases in liver enzymes
- Elevated calcium levels in the blood
- Worsening of psoriasis.

Very rare (may affect up to 1 in 10,000 people) side effects can include:

- Abnormal liver function
- Kidney failure
- Eosinophilic pneumonia
- Runny or blocked nose, sneezing, facial pressure or pain
- Bleeding or bruising more easily than normal caused by a low blood platelet count, frequent infections such as fever, severe chills, sore throat or mouth ulcers caused by a lack of white blood cells, pancytopenia (a rare type of anaemia)
- Illnesses resulting from a lack of red blood cells
- Changes in the rhythm or rate of the heart beat
- Confusion, depression or hallucinations.

Not known (frequency cannot be estimated from the data available):

- Myopia, blurred vision
- Low potassium levels
- Blood glucose increased
- Blood uric acid increased.
- Discolouration, numbness and pain in fingers or toes (Raynaud's phenomenon).
- Decrease in vision or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye or acute angle - closure glaucoma).

Other:

Concentrated urine (dark in colour), feel or are sick, have muscle cramps, confusion and fits which may be due to inappropriate anti-diuretic hormone (ADH) secretion can occur with ACE inhibitors.. If you have these symptoms contact your doctor as soon as possible.

Consult your doctor, pharmacist or nurse if you experience any of these or notice anything else that is making you feel unwell.

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. Other uncommon side effects have been reported and you should ask your doctor, pharmacist or nurse if you want to know more.

Changes may occur in your laboratory parameters (blood tests) and your doctor may need to give you blood tests to check your condition. The following changes in laboratory tests may occur low potassium in the blood, low sodium in the blood (that may lead to dehydration and low blood pressure), increase in uric acid (a substance which may cause or worsen gout), increase in blood glucose levels in diabetic patients, increased levels of liver enzymes.

AFTER TAKING PREXUM COMBI

Storage

Keep your PREXUM COMBI 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. PREXUM COMBI will not keep as well outside its container.

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 PREXUM COMBI, or the tablets have passed their expiry date, return any leftover tablets to your pharmacist for disposal.

WHAT PREXUM COMBI LOOKS LIKE

PREXUM COMBI LD 2.5/0.625 tablets are white, rod shaped tablets with a score line.

PREXUM COMBI 5/1.25 tablets are white and rod shaped.

PREXUM COMBI LD 2.5/0.625 and PREXUM COMBI 5/1.25 are supplied in quantities of thirty (30) tablets in a white bottle containing desiccants in sachet form and equipped with a red child-resistant screw-on cap.

Ingredients

Each tablet of PREXUM COMBI LD 2.5/0.625 contains 2.5 mg of perindopril arginine and 0.625 mg of indapamide hemihydrate as active ingredients.

Each tablet of PREXUM COMBI 5/1.25 contains 5 mg of perindopril arginine and 1.25 mg of indapamide hemihydrate as active ingredients.

The inactive ingredients in PREXUM COMBI LD 2.5/0.625 and PREXUM COMBI 5/1.25 tablets contain lactose monohydrate, magnesium stearate, colloidal anhydrous silica, maltodextrin, sodium starch glycollate type A, macrogol 6000, glycerol, hypromellose, titanium dioxide.

The tablets are gluten free.

Manufacturer and Sponsor

PREXUM® COMBI are products discovered by Servier Research International which are distributed in Australia by:

Servier Laboratories (Aust.) Pty Ltd

8 Cato Street

Hawthorn, Victoria 3122

Australia

PREXUM® COMBI LD 2.5/0.625 and PREXUM® COMBI 5/1.25 are registered on the Australian Register of Therapeutic Goods. Australian Register Numbers:

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