

PATIENT INFORMATION LEAFLET

COVERSYL PLUS tablet

perindopril tert-butylamine and indapamide

Contains sugar (lactose)

SCHEDULING STATUS: **S3**

Read all of this leaflet carefully before you start taking COVERSYL Plus.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **Coversyl Plus** has been prescribed to you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

- 1. What **Coversyl Plus** is and what it is used for
- 2. What you need to know before you take **Coversyl Plus**
- 3. How to take **Coversyl Plus**
- 4. Possible side effects
- 5. How to store **Coversyl Plus**
- 6. Contents of the pack and other information

1. What Coversyl Plus is and what it is used for

Coversyl Plus is a combination of two active ingredients, perindopril and indapamide. It is an anti-hypertensive and is used in the treatment of high blood pressure (hypertension) in adults.

Perindopril belongs to a class of medicines called ACE-inhibitors. These work by widening the blood vessels, which makes it easier for your heart to pump blood through them. Indapamide is a diuretic. Diuretics increase the amount of urine produced by the kidneys. However, indapamide is

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different from other diuretics, as it only causes a slight increase in the amount of urine produced.

Each of the active ingredients reduces blood pressure and they work together to control your blood pressure.

Coversyl Plus is used to treat high blood pressure.

2. What you need to know before taking **Coversyl Plus**

Do not take Coversyl Plus:

- if you are hypersensitive (allergic) to perindopril or any other ACE-inhibitor, or to indapamide or any other sulphonamides or any of the other ingredients of **Coversyl Plus**,
- if you have experienced symptoms such as wheezing, swelling of the face or tongue, intense itching or severe skin rashes with previous ACE-inhibitor treatment or if you or a member of your family have had these symptoms in any other circumstances (a condition called angioedema),
- If you have diabetes or or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren,
- if you have severe liver disease or suffer from a condition called hepatic encephalopathy (degenerative disease of the brain),
- if you have a severe kidney disease where the blood supply to your kidneys is reduced (renal artery stenosis),
- if you are receiving dialysis, or any other type of blood filtration. Depending on the machine that is used, **Coversyl Plus** may not be suitable for you.
- if you have low or high blood potassium,
- if you are suspected of having untreated decompensated heart failure (severe water retention, difficulty in breathing),
- if you are pregnant or trying to become pregnant,
- if you are breastfeeding,

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- If you have porphyria,
- If you have aortic stenosis (narrowing of the main blood vessel leading from the heart) or hypertrophic cardiomyopathy (heart muscle disease) or renal artery stenosis (narrowing of the artery supplying the kidney with blood),
- if you take lithium or potassium-sparing diuretics (spironolactone, triamterene, amiloride) or potassium salts (see Taking other medicines),
- If you are being treated with sacubitril/valsartan, a medicine for heart failure (see “Warnings and Precautions” and “Taking other medicines with **Coversyl Plus**”).
- If you take fluoroquinolones (antibiotics)

Warnings and precautions

Take special care,

- if you have aortic stenosis (narrowing of the main blood vessel leading from the heart) or hypertrophic cardiomyopathy (heart muscle disease) or renal artery stenosis (narrowing of the artery supplying the kidney with blood),
- if you have heart failure or any other heart problems,
- if you have problems with your kidneys or if you are receiving dialysis,
- if you have abnormally increased levels of a hormone called aldosterone in your blood (primary aldosteronism),
- if you have liver problems,
- if you suffer from a collagen disease such as systemic lupus erythematosus (a type of collagen disease) or scleroderma,
- if you have atherosclerosis (hardening of the arteries),
- if you suffer from hyperparathyroidism (overactive parathyroid gland),
- if you suffer from gout,
- if you have diabetes,
- if you are on a salt restricted diet or use salt substitutes which contain potassium,

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- if you take lithium or potassium-sparing drugs (spironolactone, triamterene) or potassium supplements as their use with **Coversyl Plus** should be avoided (see “Taking other medicines”),
- if you are elderly,
- if you have had photosensitivity reactions,
- if 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 the treatment and see a doctor immediately.

if you are taking any of the following medicines used to treat high blood pressure:

- an “angiotensin II receptor blocker” (ARBs) (also known as sartans - for example valsartan, telmisartan, irbesartan), in particular if you have diabetes-related kidney problems,
- aliskiren,
- Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals,
- if you are of black origin since you may have a higher risk of angioedema and this medicine may be less effective in lowering your blood pressure than in non-black patients,
- if you are a haemodialysis patient dialysed with high-flux membranes.
- if you are taking any of the following medicines, the risk of angioedema is increased:
 - racecadotril (used to treat diarrhoea),
 - sirolimus, everolimus, temsirolimus and other drugs belonging to the class of so-called mTOR inhibitors (used to avoid rejection of transplanted organs),
 - sacubitril (available as fixed-dose combination with valsartan), used to treat long-term heart failure.
 - Contact your doctor to re-evaluate your treatment if you are treated with ACE-inhibitors/Angiotensin receptor blockers together with fluoroquinolone antibiotic.

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Angioedema

Angioedema (a severe allergic reaction with swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing) has been reported in patients treated with ACE-inhibitors, including **Coversyl Plus**. This may occur at any time during treatment. If you develop such symptoms, you should stop taking Perindopril/Indapamide Arrow lab and see a doctor immediately. (See Possible side effects.)

You must tell your doctor if you think that you are (or might become) pregnant. **Coversyl Plus** is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see Pregnancy section).

When you are taking **Coversyl Plus** you should also inform your doctor or the medical staff:

- if you are to undergo anaesthesia and/or surgery,
- if you have recently suffered from diarrhoea or vomiting, or are dehydrated, your potassium levels should be monitored regularly. You may experience a sudden drop in blood pressure,
- if you are to undergo dialysis or LDL apheresis (which is removal of cholesterol from your blood by a machine),
- if you are going to have desensitisation treatment to reduce the effects of an allergy to bee or wasp stings,
- if you are to undergo a medical test that requires injection of an iodinated contrast agent (a substance that makes organs like kidney or stomach visible on an X-ray).
- if you have changes in your vision or pain in one or both of your eyes while taking **Coversyl Plus**. This could be a sign that you are developing glaucoma, increased pressure in your eye(s).

You should discontinue **Coversyl Plus**. This could treatment and seek medical attention.

Athletes should be aware that **Coversyl Plus** contains an active ingredient (indapamide) which may give a positive reaction in drug tests.

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Children and adolescents:

Coversyl Plus should not be given to children or adolescent under 18 years of age.

Other medicines and Coversyl Plus

Always tell your healthcare professional if you are taking any other medicine. (This includes complimentary or traditional medicines).

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

You should avoid taking **Coversyl Plus** with:

- lithium (used to treat mania or depression),
- aliskiren (medicine used to treat hypertension) if you have no diabetes mellitus or kidney problems,
- potassium-sparing diuretics (spironolactone, triamterene, amiloride), potassium salts, other medicines which can increase potassium in your body (such as heparin and co-trimoxazole also known as trimethoprim/sulfamethoxazole).
- estramustine (used in cancer therapy),
- other medicines used to treat high blood pressure: angiotensin-converting-enzyme inhibitors and angiotensin receptor blockers.

Treatment with **Coversyl Plus** can be affected by other medicines. Make sure to tell your doctor if you are taking any of the following medicines as special care may be required:

- other medicines for treating high blood pressure, including angiotensin II receptor blocker (ARB) or aliskiren or diuretics (medicines which increase the amount of urine produced by the kidneys),
- potassium-sparing drugs used in the treatment of heart failure: eplerenone and spironolactone at doses between 12,5 mg to 50 mg per day,

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- medicines, which are most often used to treat diarrhoea (racecadotril) or avoid rejection of transplanted organs (sirolimus, everolimus, temsirolimus and other drugs belonging to the class of so-called mTor inhibitors).
- sacubitril/valsartan (used to treat long-term heart failure). See sections “Do not take **Coversyl Plus**” and “Warnings and Precautions”.
- anaesthetic medicines,
- iodinated contrast agent,
- moxifloxacin, sparfloxacin (antibiotic: medicine used to treat infection),
- methadone (used to treat addiction),
- procainamide (for the treatment of an irregular heart beat),
- allopurinol (for the treatment of gout),
- mizolastine, astemizole (antihistamines for hay fever or allergies),
- corticosteroids used to treat various conditions including severe asthma and rheumatoid arthritis,
- immunosuppressants used for the treatment of auto-immune disorders or following transplant surgery to prevent rejection (e.g. ciclosporin, tacrolimus),
- erythromycin by injection (an antibiotic),
- halofantrine (used to treat certain types of malaria),
- pentamidine (used to treat pneumonia),
- injectable gold (used to treat rheumatoid polyarthritis),
- vincamine (used to treat symptomatic cognitive disorders in elderly, including memory loss),
- bepridil (used to treat angina pectoris),
- sultopride (antipsychotic treatment),
- medicines used for heart rhythm problems (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol),
- cisapride, diphemanil (used to treat gastric and digestive problems),
- digoxin or other cardiac glycosides (for the treatment of heart problems),

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- baclofen (to treat muscle stiffness occurring in diseases such as multiple sclerosis),
- medicines to treat diabetes such as insulin, metformin or gliptins,
- calcium, including calcium supplements,
- stimulant laxatives (e.g. senna),
- non-steroidal anti-inflammatory drugs (e.g. ibuprofen) or high dose salicylates (e.g. aspirin),
- amphotericin B by injection (to treat severe fungal disease),
- medicines to treat mental disorders such as depression, anxiety, schizophrenia...(e.g. tricyclic antidepressants, neuroleptics), (such as amisulpride, sulpiride, sultopride, tiapride, haloperidol, droperidol)),
- tetracosactide (to treat Crohn's disease),
- trimethoprim (for the treatment of infections),
- vasodilators including nitrates (products that make the blood vessels become wider),
- medicines used for the treatment of low blood pressure, shock or asthma (e.g. ephedrine, noradrenaline or adrenaline).

Coversyl Plus with food and drink

Coversyl Plus should be taken in the morning before a meal.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding , think you may be pregnant or planning to have a baby, please consult your doctor, pharmacist or other health care professional for advice before taking this medicine.

Ask your doctor or pharmacist for advice before taking any medicine.

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Pregnancy:

Coversyl® Plus must not be taken while pregnant. Should you become pregnant or contemplate pregnancy while using **Coversyl® Plus**, consult your doctor without delay.

The switch to an alternative treatment should be initiated as soon as possible.

Breastfeeding: You must not take **Coversyl Plus** if you are breastfeeding.

Tell your doctor immediately if you are breastfeeding or about to start breastfeeding. See your doctor immediately.

Driving and using machines

When driving vehicles or operating machines it should be taken into account that occasionally dizziness or weakness may occur. If affected, your ability to drive or to operate machinery may be impaired.

Coversyl Plus contains lactose

Coversyl Plus contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **Coversyl Plus**.

3. How to take Coversyl Plus

Do not share medicines prescribed for you with any other person.

Always take **Coversyl Plus** exactly as your doctor has instructed you.

You should check with your doctor or pharmacist if you are unsure.

The recommended dosage is one tablet orally taken in the morning before breakfast.

Your doctor will tell you how long your treatment with **Coversyl Plus** will last. Do not stop treatment early because this could cause your blood pressure to increase. If you have the impression that the effect of **Coversyl Plus** is too strong or too weak, tell your doctor or pharmacist.

Your doctor may decide to modify the dosage regimen if you suffer from kidney function impairment.

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If you take more Coversyl Plus than you should:

The most likely effect in case of overdose is low blood pressure. If marked low blood pressure occurs (symptoms such as dizziness or faintness), lying down with the legs raised can help.

In the event of overdosage, consult your doctor or pharmacist.

If neither is available seek help at the nearest hospital or poison control centre.

If you forget to take Coversyl Plus:

It is important to take **Coversyl Plus** every day as regular treatment is more effective. However, if you forget to take a dose of **Coversyl Plus**, take the next dose at the usual time.

Do not take a double dose to make up for forgotten individual doses.

If you stop taking Coversyl Plus

As the treatment for high blood pressure is usually life-long, you should discuss with your doctor before stopping **Coversyl Plus**.

4. Possible side effects

Coversyl Plus can have side effects.

Not all side effects reported for Coversyl Plus are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happen stop taking Coversyl Plus and tell your doctor immediately or go to your nearest casualty department at your nearest hospital:

- Severe dizziness or fainting due to low blood pressure,
- Bronchospasm (tightening of the chest, wheezing and shortness of breath),
- Swelling off the face, lips, mouth, tongue or throat, difficulty in breathing(angioedema) (See section 2 "Warnings and precautions"),

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- Severe skin reactions including erythema multiforme (a skin rash which often starts with red itchy patches on your face, arms or legs) or intense skin rash, hives, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, inflammation of mucous membranes (Stevens Johnson Syndrome) or other allergic reactions,
- Cardiovascular disorders (irregular heartbeat, angina pectoris (pains to the chest, jaw and back, brought on by physical effort), heart attack)
- Weakness of arms or legs, or problems speaking which could be a sign of a possible stroke,
- Inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell,
- Yellowing of the skin or eyes (jaundice) which could be a sign of hepatitis,
- Life-threatening irregular beat,
- Disease of the brain caused by liver illness (Hepatic encephalopathy),

In decreasing order of frequency, other side-effects of **Coversyl Plus** can include:

- Frequent:

Skin reactions in subjects predisposed to allergic and asthmatic reactions, headache, dizziness, vertigo, pins and needles, vision disturbances, tinnitus (sensation of noises in the ears), light-headedness due to low blood pressure, cough, shortness of breath, gastro-intestinal disorders (nausea, abdominal pain, anorexia, vomiting, stomach pain, taste disturbances, dry mouth, dyspepsia or difficulty of digestion, diarrhoea, constipation, allergic reactions (such as skin rash, itching), cramps, feeling of tiredness.

- Less frequent:

Mood swings, sleep disturbances, , urticaria (hives – raised itchy red spots), purpura (red pinpoints on skin), formation of blisters, kidney problems, impotence, sweating, an excess of eosinophils (a type of white blood cells), change in laboratory parameters: high blood level of potassium reversible on discontinuation, low blood level of sodium, somnolence (sleepiness), fainting,

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palpitations (awareness of your heartbeat), tachycardia (fast heartbeat), hypoglycaemia (very low blood sugar level) in case of diabetic patients, vasculitis (inflammation of blood vessels), dry mouth, photosensitivity reactions (increased sensitivity of the skin to sun), arthralgia (joint pain), myalgia (muscle pain), chest pain, malaise, peripheral oedema, fever, increased blood urea, increased blood creatinine, fall.

Worsening of psoriasis, changes in laboratory blood tests (increased level of liver enzymes, high level of serum bilirubin, high level of calcium in the blood), fatigue.

Confusion, eosinophilic pneumonia (a rare type of pneumonia), blocked up or runny nose, severe kidney problems, changes in blood values such as a lower number of white and red blood cells, lower haemoglobin, lower number of blood platelets, high level of calcium in the blood, abnormal hepatic function. If you suffer from systemic lupus erythematosus (a type of collagen disease), this might get worse.

Abnormal ECG heart tracing, changes in laboratory parameters: low potassium levels, high uric acid levels and high sugar levels in the blood, short sightedness (myopia), blurred vision, visual impairment, discolouration, numbness and pain in fingers or toes (Raynaud's phenomenon).

Disorders of the blood, kidney, liver or pancreas and changes in laboratory parameters (blood tests) can occur. Your doctor may need to give you blood tests to monitor your condition.

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

If you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"** found online under SAHPRA's publications <https://www.sahpra.org.za/Publications/Index/8>. By

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reporting side effects, you can help provide more information on the safety of

Coversyl Plus.

5. How to store Coversyl Plus

Store all medicine out of reach of children.

Store at or below 25 °C in a dry place.

Keep the container tightly closed.

Do not store in bathrooms.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Coversyl Plus contains

- The active substances are perindopril tert-butylamine and indapamide. One tablet contains 4mg perindopril tert-butylamine (corresponding to 3,338 mg perindopril) and 1,25 mg indapamide.
- The other ingredients in the tablet are: lactose monohydrate, magnesium stearate (E470B), colloidal hydrophobic silica and microcrystalline cellulose.

What Coversyl Plus looks like and contents of the pack

Coversyl Plus: White, 8-mm x 4-mm rod-shaped tablets.

Blister packs of clear PVC and aluminium with 30 tablets in a carton .

REGISTRATION NUMBER:

33/7.1.3/0363

Holder of certificate of registration

NAME AND ADDRESS OF REGISTRATION HOLDER:

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