

COVINACE TABLET 4MG

Perindopril tert-butylamine 4mg

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What Covinace Tablet is used for

- to treat symptomatic heart failure (when the heart is unable to pump enough blood to meet the body's needs),
- to treat high blood pressure (hypertension),
- to reduce the risk of cardiac events, such as heart attack, in patients with stable coronary artery disease (a condition where the blood supply to the heart is reduced or blocked) and who have already had a heart attack and/or bypass surgery or a procedure to dilate the coronary arteries.

How Covinace Tablet works

Covinace Tablet is an angiotensin converting enzyme (ACE) inhibitor. These work by widening the blood vessels, which makes it easier for the heart to pump blood through them.

Before you use Covinace Tablet

When you must not use it

Do not take this medicine if:

- you are allergic to *perindopril* or any other ingredients of this medicine (listed in 'Product Description'), or to any other ACE inhibitor.
- you have experienced symptoms such as wheezing, swelling of the face, tongue or throat, 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).
- you are more than 3 months pregnant (It is also better to avoid Covinace Tablet

in early pregnancy – see pregnancy and breast-feeding sections)

- you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.
- you are having dialysis or any other type of blood filtration. Depending on the machine that is used, Covinace Tablet may not be suitable for you.
- you have kidney problems where the blood supply to your kidneys is reduced (renal artery stenosis).
- you are being treated with sacubitril/valsartan, a medicine for heart failure.

Before you start to use it

Take special care with Covinace Tablet:

Talk to your doctor, pharmacist, or nurse before taking Covinace Tablet 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)
- have any other heart problems
- have liver problems
- have kidney problems or if you are receiving dialysis
- have abnormally increased levels of a hormone called aldosterone in your blood (primary aldosteronism)
- suffer from a collagen vascular disease such as systemic lupus erythematosus or scleroderma
- have diabetes
- are on a salt restricted diet or use salt substitutes which contain potassium
- are going to have a general anesthetic and/or major surgery
- are to undergo LDL apheresis (which is removal of cholesterol from your blood by a machine)
- are going to have desensitization treatment to reduce the effects of an allergy to bee or wasp stings
- have recently suffered from diarrhea or vomiting, or are dehydrated
- have an intolerance to some sugars
- are taking any of the following medicines used to treat high blood pressure:

- an "angiotensin II receptor blocker" (ARB) (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 number of electrolytes (e.g. potassium) in your blood at regular intervals.

See also information under the heading 'Do not take Covinace Tablet'.

- 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.
- are taking any of the following medicines, the risk of angioedema is increased:
 - racecadotril (used to treat diarrhea).
 - 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.

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 Covinace Tablet. This may occur at any time during treatment. If you develop such symptoms, you should stop taking Covinace Tablet, tablets and see a doctor immediately. See also section 'Side effects'.

Covinace Tablet contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose

malabsorption should not take this medicinal product.

Children and adolescents

The use of perindopril in children and adolescents up to the age of 18 years is not recommended.

Pregnancy and lactation

Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or lactation before using any medicine.

Your doctor will normally advise you to stop taking Covinace Tablet before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Covinace Tablet.

Covinace Tablet is not recommended in early pregnancy and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Covinace Tablet is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

- Taking other medicines

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

Treatment with Covinace Tablet can be affected by other medicines. Your doctor may need to change your dose and/or take other precautions if you are taking any of the following:

- other medicines for high blood pressure, including angiotensin II receptor blockers (ARBs), aliskiren (see also information under the headings 'Do not take Covinace Tablet' and 'Before you start to use it'), or diuretics (medicines which increase the amount of urine produced by the kidneys).
- potassium-sparing diuretics (e.g. triamterene, amiloride) potassium

supplements or potassium-containing salt substitutes, other drugs which can increase potassium in your body (such as heparin and co-trimoxazole also known as trimethoprim/sulfamethoxazole),

- potassium-sparing diuretics used in the treatment of heart failure: eplerenone and spironolactone at doses between 12.5mg to 50mg by day,
- lithium for mania or depression,
- non-steroidal anti-inflammatory drugs (e.g. ibuprofen) for pain relief or high dose aspirin,
- medicines used in the treatment of diabetes (such as insulin, metformin or gliptines),
- baclofen (used to treat muscle stiffness in diseases such as multiple sclerosis),
- medicines to treat mental disorders such as depression, anxiety, schizophrenia etc (e.g. tricyclic antidepressants, antipsychotics),
- anesthetics,
- immunosuppressants (medicines which reduce the defense mechanism of the body) used for the treatment of autoimmune disorders or following transplant surgery (e.g. ciclosporin, tacrolimus),
- trimethoprim (for the treatment of infections),
- estramustine (used in cancer therapy),
- medicines, which are most often used to treat diarrhea (racecadotril) or avoid rejection of transplanted organs (sirolimus, everolimus, temsirolimus and other drugs belonging to the class of so-called mTOR inhibitors). See section 'Take special care with Covinace Tablet'
- sacubitril/valsartan (used to treat long-term heart failure). See sections 'Do Not Take Covinace Tablet'
- procainamide (for the treatment of an irregular heartbeat)
- allopurinol (for the treatment of gout)
- 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)

- gold salts, especially with intravenous administration (used to treat symptoms of rheumatoid arthritis)

How to use Covinace Tablet

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

The usual doses are as follows:

High blood pressure: the usual starting and maintenance dose is 4mg once daily. After one month, this can be increased to 8mg per day if required. 8mg per day is the maximum recommended dose for high blood pressure.

If you are over the age of 65, the usual starting dose is 2mg once daily. After one month, this can be increased to 4mg per day and then if necessary to 8mg per day.

Heart failure: the usual starting dose is 2mg once daily. After two weeks, the dose can be increased to 4mg, which is the maximum recommended dose for treating heart failure.

Stable coronary artery disease: the usual starting dose is 4mg once daily. After two weeks, this can be increased to 8mg once daily, which is the maximum recommended dose in this indication.

If you are over the age of 65, the usual starting dose is 2mg once daily. After one week, this can be increased to 4mg once daily and after a further week to 8mg once daily.

- When to use it

Swallow your tablet with a glass of water, preferably at the same time each day, in the morning, before a meal.

Use as directed by your doctor or pharmacist.

- How long to use it

Use Covinace Tablet for the duration that the doctor recommends.

As the treatment with Covinace Tablet is usually life-long, you should discuss with your doctor before stopping this medicinal product.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist, or nurse.

- If you forget to use it

It is important to take your medicine every day as regular treatment works better. However, if you forget to take a dose of Covinace Tablet, take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital if you or anyone else may have used too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause low blood pressure. If marked low blood pressure occurs (symptoms such as dizziness or faintness), lying down with the legs raised can help.

While you are using it

- Things you must do

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using Covinace Tablet.

Tell your doctor immediately if you become pregnant while using this medication.

Take Covinace Tablet only with a doctor's prescription.

- Things you must not do

Do not stop using the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Covinace Tablet to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

Covinace Tablet usually does not affect alertness but dizziness or weakness due to low blood pressure may occur in certain patients. If you are affected in this way, your ability to drive or to operate machinery may be impaired.

Side effects

Like all medicines, Covinace Tablet can cause side effects, although not everybody gets them.

If you experience one of the potentially serious side effects, stop taking Covinace Tablet and see a doctor immediately:

Endocrine disorders:

Syndrome of Inappropriate Antidiuretic Hormone (SIADH); A condition in which your body makes too much antidiuretic hormone (ADH)

Vascular disorders:

Severe dizziness or fainting due to low blood pressure, vasculitis (inflammation of blood vessels), flushing, weakness of arms or legs, or problems speaking which could be a sign of a possible stroke, Raynaud's phenomenon

Blood and the lymphatic system disorders:

Excess of eosinophils (a type of white blood cells), changes in blood values such as lower number of white and red blood cells, lower hemoglobin, lower number of blood platelets, and hemolytic anemia in patients with congenital deficiency of G-6PDH.

Metabolism and Nutrition Disorders:

High blood level of potassium reversible on discontinuation, low level of sodium, hypoglycemia (very low blood sugar level) in case of diabetic patients, increased blood urea and increased blood creatinine.

Psychiatric Disorders:

Mood swings, sleep disturbances and depression.

Nervous System Disorders:

Dizziness, headache, pins and needles, vertigo, somnolence, fainting and confusion

Eye Disorders:

Vision disturbances

Ear and labyrinth Disorders:

Sensation of noises in the ears

Cardiac Disorders:

Sensation of irregular heartbeat, abnormal fast heartbeat, chest pain or discomfort that keeps coming back, abnormal heartbeat, heart attack (possibly secondary to excessive hypotension in high-risk patients)

Respiratory, Thoracic and Mediastinal Disorders:

Cough, shortness of breath, difficulty in breathing (bronchospasm), eosinophilic pneumonia, and runny nose.

Gastrointestinal Disorders:

Abdominal pain, constipation, diarrhea, dysgeusia, dyspepsia, nausea, vomiting, dry mouth, and pancreatitis

Hepato-biliary Disorders:

Hepatitis either cytolytic or cholestatic

Skin and Subcutaneous Tissue Disorders:

Pruritus, rash, urticaria, angioedema (swelling of face extremities, lips, mucous membranes, tongue, glottis and/or larynx), extreme sensitivity to ultraviolet (UV) rays from sun or other light sources, rare autoimmune disorder that results in skin blistering, excessive sweating, psoriasis worsening and skin rash which often starts with red itchy patches on your face, arms or legs.

Musculoskeletal and Connective Tissue Disorders:

Muscle cramps, joint stiffness, and muscle pain

Renal and Urinary Disorders:

Poor function of kidney, acute kidney failure, anuria (absence of urine production), oliguria (low urine output)

Reproductive System and Breast Disorders:

Erectile dysfunction

General Disorders and Administration Site Condition:

Physical weakness or lack of energy, chest pain, general feeling of discomfort, swelling in your legs or hands and fever.

Investigations:

Blood urea increased, blood creatinine increased, blood bilirubin increased, and hepatic enzyme increased.

Injury, poisoning and procedural complications:

Fall

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Concentrated urine (dark in color), 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.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring visiting the website npra.moh.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Covinace Tablet

- Storage

Keep out of the reach and sight of children.

Do not use after the expiry date, which is stated on the carton and blister.

The expiry date refers to the last day of the month.

Store below 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

White to off white oblong tablet with scored on both sides.

- Ingredients

- Active ingredient(s)
Perindopril tert-butylamine 4mg

- Inactive ingredients
Microcrystalline cellulose M101, Agglomerated Lactose monohydrate, Magnesium stearate and Hydrophobic Colloidal silicon dioxide

- MAL number(s):
MAL06041482AZ

Manufacturer and Product Registration Holder

Pharmaniaga Manufacturing Berhad (198001006232),
11A, Jalan P/1, Kawasan Perusahaan Bangi, 43650, Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia.

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