

COVINACE 8MG TABLET

Perindopril tert-butylamine 8mg

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What COVINACE 8MG is used for

COVINACE 8MG is used:

- 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 8MG works

COVINACE 8MG 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 8MG

- When you must not use it

Do not take COVINACE 8MG:

- if you are allergic to perindopril or any of the other ingredients of this medicine (listed in section 'Product description'), or to any other ACE inhibitor
- if 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)

- if you are more than 3 months pregnant (It is also better to avoid COVINACE 8MG, tablet in early pregnancy – see Pregnancy and Breast-feeding sections)
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren
- if you are having dialysis or any other type of blood filtration. Depending on the machine that is used, COVINACE 8MG may not be suitable for you
- if you have kidney problems where the blood supply to your kidneys is reduced (renal artery stenosis)
- if you are being treated with sacubitril/valsartan, a medicine for heart failure

Before you start to use it

Take special care with COVINACE 8MG tablet:

Talk to your doctor, pharmacist or nurse before taking COVINACE 8MG 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 anaesthetic and/or major surgery
- are to undergo LDL apheresis (which is removal of cholesterol from your blood by a machine)
- are going to have desensitisation treatment to reduce the effects of an allergy to bee or wasp stings
- have recently suffered from diarrhoea 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 amount of electrolytes (e.g. potassium) in your blood at regular intervals.

See also information under the heading 'Do not take COVINACE 8MG'.

- 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

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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 8MG, tablets. This may occur at any time during treatment. If you develop such symptoms, you should stop taking COVINACE 8MG, tablets and see a doctor immediately. See also section 'Side effects'.

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.

- Taking other medicines

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

Treatment with COVINACE 8MG 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 8MG' 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 12.5 mg to 50 mg 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 or metformin)
- 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),
- immunosuppressants (medicines which reduce the defence mechanism of the body) used for the treatment of auto-immune 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 8MG tablet"
- sacubitril/valsartan (used to treat long-term heart failure). See sections "Do not take Covinace 8mg"
- procainamide (for the treatment of an irregular heart beat)
- 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 8MG

- How much to use

Always take this medicine exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure. Your doctor will decide on the correct dose for you.

The usual doses are as follows:

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

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

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

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

- 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.

- How long to use it

As the treatment with COVINACE

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8MG 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 a regular treatment works better. However if you forget to take a dose of COVINACE 8MG, take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

- *If you use too much (overdose):*

If you take too many tablets, contact your nearest accident and emergency department or tell your doctor immediately. 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.

While you are using COVINACE 8MG

- *Things you must do*

Pregnancy

You must tell your doctor if you think that you are (or might become) pregnant.

Your doctor will normally advise you to stop taking COVINACE 8MG, 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 8MG.

COVINACE 8MG 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.

Breastfeeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. COVINACE 8MG 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.

- *Things you must not do*

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

Do not take any new medicines without consulting your doctor.

Do not give COVINACE 8MG to anyone else, even if they have the same symptoms or condition as you.

- *Things to be careful of*

Driving and using machines

COVINACE 8MG 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 8MG can cause side effects, although not everybody gets them.

If you experience one of the potentially serious side effects, stop taking COVINACE 8MG and see a doctor immediately:

- swelling of the face, lips, mouth, tongue or throat, difficulty in breathing (angioedema)
- severe dizziness or fainting due to low blood pressure
- unusually fast or irregular heartbeat, chest pain (angina) or heart attack
- weakness of arms or legs, or problems speaking which could be a sign of a possible stroke
- sudden wheeziness, chest pain, shortness of breath, or difficulty in breathing (bronchospasm)
- 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
- skin rash which often starts with red itchy patches on your face, arms or legs (erythema multiforme)

Tell your doctor if you notice any of the following side effects:

- headache
- dizziness
- vertigo
- pins and needles
- vision disturbances
- tinnitus (sensation of noises in the ears)
- cough
- shortness of breath (dyspnoea)
- gastro-intestinal disorders (nausea, vomiting, abdominal pain, taste disturbances, dyspepsia or difficulty of digestion, diarrhoea, constipation)
- allergic reactions (such as skin rashes, itching)
- muscle cramps
- feeling of weakness
- mood swings
- sleep disturbances
- dry mouth
- intense itching or severe skin rashes
- formation of blister clusters over the skin
- kidney problems
- impotence
- sweating
- excess of eosinophils (a type of white blood cells)
- somnolence
- fainting
- palpitations
- tachycardia
- vasculitis (inflammation of blood vessels)
- photosensitivity reaction (increased sensitivity of the skin to sun)
- arthralgia (joint pain)
- myalgia (muscle pain)
- chest pain
- malaise
- oedema peripheral
- fever
- fall
- changes in laboratory parameters:
- high blood level of potassium
- reversible on discontinuation, low level of sodium, hypoglycaemia (very low blood sugar level) in

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- case of diabetic patients, increased blood urea and increased blood creatinine.
- changes in laboratory parameters: high blood level of potassium reversible on discontinuation, low level of sodium, hypoglycaemia (very low blood sugar level) in case of diabetic patients,
- increased blood urea and increased blood creatinine.
- psoriasis worsening
- changes in laboratory parameters: increased level of liver enzymes, high level of serum bilirubin.
- confusion
- eosinophilic pneumonia (a rare type of pneumonia)
- rhinitis (blocked up or runny nose)
- acute renal failure
- changes in blood values such as lower number of white and red blood cells, lower haemoglobin, lower number of blood platelets.

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

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.

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

Storage and Disposal of COVINACE 8MG

- 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

Do not throw away any medicines via wastewater or household waste.

Ask your pharmacist how to dispose of unused medicines. These measures will help protect the environment.

Product Description

- What it looks like

White to off white, round, biconvex tablet, with intersected breakline on one side and plain on the other.

- Ingredients

- Active ingredient(s):

Perindopril tert-butylamine 8mg.

- Inactive ingredients:

Lactose monohydrate, microcrystalline cellulose, colloidal silicone dioxide, magnesium stearate.

- MAL number

MAL14075036AZ

Manufacturer

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

Product Registration Holder

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