

Package leaflet: Information for the user

Percarnil 4 mg Tablets Percarnil 8 mg Tablets

perindopril tert-butylamine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Percarnil is and what it is used for

Percarnil contains the active substance perindopril tert-butylamine which belongs to a group of medicines called ACE inhibitors. These work by widening the blood vessels. This makes it easier for your heart to pump blood through the body.

Percarnil 4 mg Tablets are used to:

- treat high blood pressure (hypertension)
- treat heart failure (a condition where the heart is unable to pump enough blood to meet the body's needs)
- 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 an operation to improve the blood supply to the heart by widening the vessels that supply it.

Percarnil 8 mg Tablets are used to:

- treat high blood pressure (hypertension)
- 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 an operation to improve the blood supply to the heart by widening the vessels that supply it.

2. What you need to know before you take Percarnil

Do not take Percarnil:

- If you are allergic to perindopril or any of the other ingredients of this medicine (listed in section 6) 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 Percarnil in early pregnancy (see pregnancy section).
- If you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

Warnings and precautions

Talk to your doctor or pharmacist before taking Percarnil:

- if you have aortic stenosis (narrowing of the main 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 any other heart problems,
- if you have liver problems,
- if you have kidney problems or if you are receiving dialysis,
- if you suffer from a collagen vascular disease such as systemic lupus erythematosus or scleroderma,
- if you have diabetes
- if you are on a salt restricted diet or use salt substitutes which contain potassium,
- if you are going to have a general anaesthetic and/or major surgery,
- if you are to undergo 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 have recently suffered from diarrhea or vomiting, or are dehydrated,
- if you are taking any of the following medicines, the risk of angioedema (rapid swelling under the skin in area such as the throat) 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)
- 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.

See also information under the heading ‘Do not take Percarnil’.

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.

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 Percarnil. This may occur at any time during treatment. If you develop such symptoms, you should stop taking Percarnil and see a doctor immediately. See also section 4. You must tell your doctor if you think you are (or might become) pregnant. Percarnil 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 that stage (see pregnancy section).

Children and adolescents

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

Other medicines and Percarnil

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Treatment with Percarnil can be affected by other medicines. Your doctor may need to change your dose and/or to take other precautions. These include:

- other medicines for high blood pressure, including angiotensin II receptor blocker (ARB), aliskiren (see also information under the headings “Do not take Percarnil” and “Warnings and precautions”), or diuretics (medicines which increase the amount of urine produced by the kidneys), potassium-sparing drugs (spironolactone, amiloride, triamterene), potassium supplements or potassium-containing salt substitutes, other drugs which can increase potassium in your body:
 - heparin (medicines used to thin blood),
 - trimethoprim and co-trimoxazole also known as trimethoprim/sulfamethoxazole, (for the treatment of infections),
- potassium-sparing drugs 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 to treat diabetes (such as insulin or metformine),
- 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),
- estramustine (used in cancer therapy),
- allopurinol (for the treatment of gout),
- procainamide (for the treatment of an irregular heart beat),
- 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 salt, especially with intravenous administration (used to treat symptoms of rheumatoid arthritis).
- medicines, which is 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 “Warnings and precautions”

Ask your doctor if you are not sure what these medicines are. Tell the doctor if you have taken any of the medicines listed above in the past, but have now stopped.

Percarnil with food and drink

It is preferable to take Percarnil tablets before a meal.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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 Percarnil before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Percarnil. Percarnil 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. Percarnil 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.

Driving and using machines

Percarnil 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 abilities to drive or to operate machinery may be impaired.

Percarnil 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.

3. How to take Percarnil

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Swallow your tablet with a glass of water, preferably at the same time each day, in the morning, before a meal. Your doctor will decide on the correct dose for you.

The recommended dosages are as following:

High blood pressure:

The recommended starting and maintenance dose is 4 mg once daily. After one month, this may be increased to 8 mg once a day if required. 8 mg a day is the maximum recommended dose for high blood pressure. If you are 65 or older, the recommended starting dose is 2 mg once a day. After a month this can be increased to 4 mg once a day and then if necessary to 8 mg once daily.

Heart failure: The recommended starting dose 2 mg Percarnil once daily. After 2 weeks, this can be increased to 4 mg once a day, which is the maximum recommended dose for heart failure. The 8 mg strength is not suitable for treatment of this condition.

Stable coronary artery disease:

The recommended starting dose is 4 mg Percarnil once daily. After two weeks, this may be increased to 8 mg once daily, which is the maximum recommended dose for this indication. If you are 65 or older, the recommended starting dose is 2 mg once a day. After a week this can be increased to 4 mg once a day and after a further week to 8 mg once daily.

Use in children and adolescents

Use in children and adolescents is not recommended.

If you take more Percarnil than you should

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 which can make you feel dizzy or faint. If this happens, lying down with the legs raised can help.

If you forget to take Percarnil

It is important to take your medicine every day as regular treatment works better. However, if you forget to take a dose of Percarnil, take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Percarnil

As the treatment with Percarnil 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 or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking this medicine and see your doctor immediately, if you experience any of the following side effects that can be serious:

- swelling of the face, lips, mouth, tongue or throat
- difficulty in breathing (angioedema) (See section 2 “Warnings and precautions”) (Uncommon – may affect up to 1 in 100 people),
- severe dizziness or fainting due to low blood pressure (Common – may affect up to 1 in 10 people),
- unusual fast or irregular heartbeat, chest pain (angina) or heart attack (Very rare – may affect up to 1 in 10,000 people),
- weakness of arms or legs, or problems speaking which could be a sign of a possible stroke (Very rare – may affect up to 1 in 10,000 people),
- sudden wheeziness, chest pain, shortness of breath, or difficulty in breathing (bronchospasm) (Uncommon – may affect up to 1 in 100 people),
- inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell (Very rare – may affect up to 1 in 10,000 people),
- yellowing of the skin or eyes (jaundice) which could be a sign of hepatitis (Very rare – may affect up to 1 in 10,000 people), skin rash which often starts with red itchy patches on your face, arms or legs (erythema multiforme) (Very rare – may affect up to 1 in 10,000 people).

Tell your doctor if you notice any of the following side effects:**Common** (may affect up to 1 in 10 people)

- 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.

Uncommon (may affect up to 1 in 100 people)

- 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,
- change 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.

Rare (may affect up to 1 in 1,000 people)

- changes in laboratory parameters: Increased level of liver enzymes, high level of serum bilirubin,
- psoriasis worsening

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

- confusion,
- eosinophilic pneumonia (a rare type of pneumonia),
- rhinitis (blocked up or runny nose),
- acute kidney failure,
- changes in blood values such as a lower number of white and red blood cells, lower haemoglobin, lower number of blood platelets.

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 directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Percarnil

Keep this medicine out of the sight and reach of children.
Do not store above 30°C.

Do not use this medicine after the expiry date which is stated on the carton after “do not use after” or “exp”. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Percarnil contains

- The active substance is: Perindopril tert-butylamine.

Each Percarnil 4 mg tablet contains 4 mg of perindopril tert-butylamine salt equivalent to 3.338mg of perindopril.

Each Percarnil 8 mg tablet contains 8 mg of perindopril tert-butylamine salt equivalent to 6.676mg perindopril.

- The other ingredients (excipients) are:
Hydrophobic colloidal silica, microcrystalline cellulose, lactose and magnesium stearate.

What Percarnil looks like and contents of the pack

Percarnil 4 mg:

White, oblong tablets with a break line on both sides, ‘PP’ on one side and ‘4’ on the other.

Percarnil 8 mg:

White, round, biconvex tablets with ‘PP’ on one side and ‘8’ on the other.

Each strength of tablet is available in packaging containing 14, 20, 28, 30, 56, 60 and 90 tablets in alu-alu blister packaging.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation holder

Accord Healthcare Ireland Ltd,
Euro House,
Euro Business Park,
Little Island,
Cork T45 K857,
Ireland

Manufacturer(s)

Tillomed Laboratories Ltd
3 Howard Road, Eaton Socon, St Neots
Cambridgeshire PE19 8ET United Kingdom

Glenmark Pharmaceuticals s.r.o
Fibíchova 143, 566 17 Vysoké Mýto
Hvězdova 1716/2b, 140 78 Praha 4
Czech Republic

Aurobindo Pharma B.V hodn Aurobindo Benlux
Baarnsche Dijk 1
3741 LN Baarn
The Netherlands

Actavis Group PTC ehf
Reykjavíkurvegur 76-78
220 Hafnarfjörður
Iceland

This medicinal product is authorised in the Member States of the EEA under the following names:

Ireland	Percarnil
United Kingdom	Perindopril 2 mg Tablets
	Perindopril 4 mg Tablets
	Perindopril 8 mg Tablets

This leaflet was last revised in September 2018