

Package leaflet: Information for the user

Percarnil plus 4mg/1.25mg Tablets

(perindopril *tert*-butylamine/indapamide)

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

1. What Percarnil plus is and what it is used for

What are Percarnil plus tablets?

Percarnil plus is a combination of two active substances, perindopril and indapamide. It is an anti-hypertensive medicine used in the treatment of high blood pressure (hypertension).

What are Percarnil plus tablets used for?

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 different from other diuretics, as it only causes a slight increase in the amount of urine produced. Each of the active substances reduces blood pressure and they work together to control your blood pressure.

2. What you need to know before you take Percarnil plus

Do not take Percarnil plus:

- if you are allergic to perindopril, indapamide or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to other ACE inhibitors or sulphonamides
- 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 severe liver disease or suffer from a condition called hepatic encephalopathy (a degenerative disease of the brain)
- if you have severe kidney disease or if you are having dialysis
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.
- if you have low or high blood potassium
- if you are suspected of having untreated decompensated heart failure (symptoms can include severe water retention and difficulty in breathing)

- if you are in the last 6 months of pregnancy (see also the section “pregnancy and breast-feeding” below).

Tell your doctor if you are breast-feeding or about to start breast-feeding. Percarnil plus is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breastfeed, especially if your baby is newborn, or was born prematurely.

Warnings and precautions

Talk to your doctor or pharmacist before taking Percarnil plus

- if you have aortic stenosis (narrowing of the main blood vessel leading from the heart), hypertrophic cardiomyopathy (heart muscle disease) or renal artery stenosis (narrowing of the artery supplying the kidney with blood)
- if you have liver problems
- if you suffer from a collagen disease such as systemic lupus erythematosus or scleroderma
- if you have atherosclerosis (hardening of the arteries)
- if you suffer from hyperparathyroidism (a condition where your parathyroid gland does not work properly)
- if you suffer from gout
- if you have diabetes
- if you are on a salt restricted diet or are using salt substitutes which contain potassium
- if you are taking lithium
- if you are taking potassium-sparing diuretics (spironolactone, triamterene) as their use with Percarnil plus tablets should be avoided (see “Other medicines and Percarnil plus”).
- if you have any other heart problems or problems with your kidneys
- 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, temisartan, irnesartan), 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 plus”

You must tell your doctor if you think that you are (or might become) pregnant. Percarnil plus is not recommended in early pregnancy and may cause serious harm to your baby after 3 months of pregnancy (see also the section “Pregnancy and breast-feeding” below).

When you are taking Percarnil plus tablets, you should also inform your doctor or the medical staff if you:

- are to undergo anaesthesia and/or surgery
- have recently suffered from diarrhoea or vomiting or are dehydrated
- are to undergo dialysis or 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 a bee or wasp sting
- are to undergo 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).

Athletes should be aware that Percarnil plus tablets contain an active substance (indapamide) which may give a positive reaction in drug tests.

Children and adolescents

Percarnil plus tablets should not be given to children.

Other medicines and Percarnil plus

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

Your doctor may need to change your dose and/or to take other precautions:

If you are taking an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings “Do not take Percarnil plus” and “Warnings and precautions”)

You should avoid taking Percarnil plus tablets with:

- lithium (used to treat depression)
- potassium-sparing diuretics (spironolactone, triamterene) and potassium salts, other drugs which can increase potassium in your body (such as heparin and co-trimoxazole also known as trimethoprim/sulfamethoxazole),

Tell your doctor if you are taking any of the following medicines as they may interact with Percarnil plus tablets:

- other medicines for treating high blood pressure
- other diuretics (“water tablets”)
- procainamide (for the treatment of an irregular heart beat)
- allopurinol (for the treatment of gout)
- terfenadine, astemizole or mizolastine (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)
- medicines for the treatment of cancer
- erythromycin by injection (an antibiotic)
- halofantrine (used to treat certain types of malaria)
- cisapride or diphermanil (used to treat gastro-intestinal disorders)
- sparfloxacin or moxifloxacin (antibiotics used to treat infections)
- methadone
- pentamidine (used to treat pneumonia)
- vincamine (used to treat memory loss in the elderly)
- bepridil (used to treat angina pectoris)
- medicines for the treatment of heart rhythm problems (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide, bretylium)
- digoxin or other cardiac glycosides (for the treatment of heart problems)
- baclofen (to treat muscle stiffness occurring in diseases such as multiple sclerosis)
- medicines to treat diabetes such as insulin or metformin
- 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 neurological disorders such as depression, anxiety and schizophrenia including tricyclic antidepressants and neuroleptics (such as amisulpride, sulpiride, sultopride, tiapride, haloperidol, droperidol)
- tetracosactide (to treat Crohn’s disease).
- gold by injection (to treat arthritis). This may also be called sodium aurothiomalate
- Anaesthetics given before or during an operation
- Contrast media given into the vein before “special” x-rays
- 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”

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.

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

Usually, your doctor will advise you to take another medicine instead of Percarnil plus, as Percarnil plus is not recommended in early pregnancy, and may cause serious harm to your baby if it is used after 3 months of pregnancy. Appropriate antihypertensive medicines must usually replace Percarnil plus before starting a pregnancy.

Percarnil plus should not be used during the 2nd and 3rd trimester of pregnancy.

Your doctor will normally advise you to stop taking Percarnil plus as soon as you know you are pregnant.

If you become pregnant during therapy with Percarnil plus, please inform and see your doctor without delay.

You must not take Percarnil plus tablets if you are breast-feeding.

Driving and using machines

Percarnil plus tablets do not usually affect alertness but different reactions such as dizziness or weakness in relation to a decrease in blood pressure may occur in certain patients. You should make sure you are not affected in this way before you drive or operate machinery.

Percarnil plus 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 plus

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The recommended dose is one tablet once a day. Your doctor may decide to modify the dosage regimen if you suffer from renal impairment. It is preferable to take your tablet in the morning and before a meal. Swallow the tablet with a glass of water.

If you take more Percarnil plus tablets than you should

If you take too many tablets, contact your doctor or nearest hospital casualty department immediately. The most likely effect in case of overdose is low blood pressure. If marked low blood pressure occurs (symptoms include dizziness or faintness), it can help to lie down with your feet raised in the air.

If you forget to take Percarnil plus tablets

It is important to take your medicine every day as regular treatment is more effective. However, if you forget to take a dose of Percarnil plus tablets, 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 plus tablets

As the treatment for high blood pressure is usually life-long, you should talk 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.

The following side effects are important and will require **immediate** action if you experience them. **You should stop taking Percarnil plus and see your doctor immediately if the following symptoms occur:**

- swelling of the face, tongue and windpipe which can cause great difficulty in breathing
- a sudden allergic reaction with shortness of breath, rash, wheezing and a drop in blood pressure
- an unusually fast heart beat
- severe, extensive, blistering skin rash

The following side effects have been reported:

Common (may affect up to 1 in 10 people):

Headache, vision disturbance, dizziness, tinnitus (ringing in the ears), vertigo, light-headedness due to low blood pressure, pins and needles, shortness of breath, cough, feeling and being sick (nausea and vomiting), abdominal pain, taste disturbances, dry mouth, indigestion, diarrhoea, constipation, muscle cramps, allergic reactions (such as skin rashes, itching) and feeling of tiredness.

Uncommon (may affect up to 1 in 100 people):

Mood swings, angioedema (symptoms such as wheezing, swelling of the face or tongue), sleep disturbances, pinpoint bleeding under the skin (purpura), tightening of the chest, wheezing and shortness of breath (bronchospasm), kidney problems (renal failure), inflammation of the pancreas (pancreatitis), inflammation of the liver (hepatitis), hives, sweating, impotence. If you suffer from systemic lupus erythematosus (a type of collagen disease) this condition might get worse.

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

Psoriasis worsening.

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

Confusion, blocked up runny nose (rhinitis), eosinophilic pneumonia (a rare type of pneumonia), irregular heart beat, angina, heart attack (cardiovascular disorders), severe skin reactions such as erythema multiforme. Cases of increased sensitivity of the skin to sunlight or artificial UV light (photosensitivity) have been reported. Symptoms of sunburn may occur more quickly than normal. Blood disorders including anaemia which may make you more likely to get an infection (such as fever, sore throat or mouth ulcers) and/or bruise or bleed more easily and/or feel generally weak, look pale and short of breath.

In cases of hepatic insufficiency (liver problems), there is the possibility of the onset of hepatic encephalopathy (a degenerative disease in the brain).

Changes in blood test results may occur. Your doctor may need to check your blood tests to monitor your condition.

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 6767836. 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 plus

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP:.. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package, in order to protect from moisture.

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 plus contain

- The active substances are perindopril *tert*-butylamine and indapamide. One tablet contains 4 mg perindopril *tert*-butylamine and 1.25mg indapamide
- The other ingredients are: Lactose monohydrate, cellulose microcrystalline, silica colloidal anhydrous and magnesium stearate.

What Percarnil plus look like and contents of the pack

Percarnil plus 4mg/1.25mg tablets are white to off-white, capsule-shaped tablets, embossed with '14' on one side and '>' on the other side.

The tablets are available in blisters containing 14, 20, 28, 30, 50, 56, 60, 90, 100 or 500 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Arrow Generics Limited, Unit 2, Eastman Way, Stevenage, Hertfordshire,
SG1 4SZ, U.K.

Manufacturer:

Arrow Pharm (Malta) Limited
62 Hal Far Industrial Estate
Birzebbugia BBG06
Malta

Or

Juta Pharma GmbH
Gutenbergstraße 13
24941 Flensburg
Germany

Or

Arrow Génériques
26 avenue Tony Garnier
69007 Lyon
France

Or

Selamine Limited – T/A Arrow Generics Limited
Clonshaugh Industrial Estate
Clonshaugh, Dublin 17
Ireland

or

Actavis Ltd
BLB 016, Bulebel Industrial Estate
Zejtun, ZTN 3000
Malta

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

| | |
|-----------------|--|
| Belgium | Perindopril+Indapamide Arrow Generics 4 mg/1,25 mg, tabletten |
| Czech Republic | Perindopril/Indapamide Arrow 4 mg/1,25 mg |
| Denmark | Coprindomid |
| France | Perindopril/Indapamide Arrow 4 mg/1,25 mg, comprimé |
| Germany | Perindo-Q comp. 4/ 1,25 mg Tabletten |
| Hungary | Co-indipam 4 mg/1,25 mg tableta |
| Ireland | Percarnil plus 4 mg/1.25 mg tablets |
| Italy | Perindopril/Indapamide Arrow 4 mg/1,25 compresse |
| Malta | Percarnil 4 mg/1.25 mg tablets |
| The Netherlands | Perindopril tert-butylamine/Indapamide Arrow 4 mg/1,25 mg, tabletten |
| Poland | Co-Indipam |
| Portugal | Perindopril+Indapamida Arrowblue |
| Slovenia | Perindopril/indapamid Arrow 4 mg/1,25 mg tablete |
| Slovak Republic | Perindopril/Indapamid Arrow 4 mg/1,25 mg |
| Spain | Perindopril/Indapamida Arrow 4 mg/1,25 mg comprimidos EFG |
| United Kingdom | Percarnil 4mg/1.25mg tablets |

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