

Package leaflet: Information for the patient

bi Preterax 5mg/1.25mg film-coated tablets perindopril arginine/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 bi Preterax 5mg/1.25mg is and what it is used for
2. What you need to know before you take bi Preterax 5mg/1.25mg
3. How to take bi Preterax 5mg/1.25mg
4. Possible side effects
5. How to store bi Preterax 5mg/1.25mg
6. Contents of the pack and other information

1. What bi Preterax 5mg/1.25mg is and what it is used for

bi Preterax 5mg/1.25mg 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 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.

2. What you need to know before you take bi Preterax 5mg/1.25mg

Do not take bi Preterax 5mg/1.25mg

- if you are allergic to perindopril or any other ACE inhibitor, or to indapamide or any other sulphonamides or any of the other ingredients of this medicine (listed in section 6),
- 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 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, bi Preterax may not be suitable for you.
- if you have low blood potassium,
- if you are suspected of having untreated decompensated heart failure (severe water retention, difficulty in breathing),
- if you are more than 3 months pregnant (It is also better to avoid bi Preterax 5mg/1.25mg in early pregnancy - see "Pregnancy and Breast-feeding"),
- if you are breast-feeding,

- if you are being treated with sacubitril/valsartan, a medicine for heart failure (see “Warning and Precaution” and “Other medicines and bi Preterax 5mg/1.25mg”).

Warnings and precautions

Talk to your doctor or pharmacist before taking bi Preterax 5mg/1.25mg:

- 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 kidney problems, 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 (skin disease) such as systemic lupus erythematosus 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,
- if you take lithium or potassium-sparing drugs (spironolactone, triamterene) or potassium supplements as their use with bi Preterax 5mg/1.25mg 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.

See also information under the heading “Do not take bi Preterax 5mg/1.25mg”,

- 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 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 bi Preterax. This may occur at any time during treatment. If you develop such symptoms, you should stop taking bi Preterax and see a doctor immediately. See also section 4.

You must tell your doctor if you think that you are (or might become) pregnant. bi Preterax 5mg/1.25mg 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 and breastfeeding”).

When you are taking bi Preterax 5mg/1.25mg, 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,
- 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 bi Preterax. This could be a sign that you are developing glaucoma, increased pressure in your eye(s). You should discontinue bi Preterax treatment and seek medical attention.

Athletes should be aware that bi Preterax 5mg/1.25mg contains an active ingredient (indapamide) which may give a positive reaction in drug tests.

Children and adolescents

bi Preterax 5mg/1.25mg should not be given to children and adolescents.

Other medicines and bi Preterax 5mg/1.25mg

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

You should avoid bi Preterax 5mg/1.25mg 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 (e.g. triamterene, amiloride), potassium salts, or other drugs 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 bi Preterax 5mg/1.25mg can be affected by other medicines. Your doctor may need to change your dose and/or to take other precautions. 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 (see also information under the headings “Do not take bi Preterax 5mg/1.25mg” and “Take special care with bi Preterax 5mg/1.25mg”) 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,
- 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 “Warnings and precautions”.
- sacubitril/valsartan (used to treat long-term heart failure). See sections “Do not take bi Preterax 5mg/1.25mg” 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, terfenadine or 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),
- medicines used for heart rhythm problems (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol),
- cisapride, diphermanil (used to treat gastric and digestive problems),
- 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 , 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).

bi Preterax 5mg/1.25mg with food and drink

It is preferable to take bi Preterax 5mg/1.25mg 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 bi Preterax 5mg/1.25mg before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of bi Preterax 5mg/1.25mg. bi Preterax 5mg/1.25mg 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.

Breast-feeding

You must not take bi Preterax 5mg/1.25mg if you are breast-feeding.

Tell your doctor immediately if you are breast-feeding or about to start breast-feeding.

See your doctor immediately.

Driving and using machines

bi Preterax 5mg/1.25mg usually does not affect alertness but different reactions such as dizziness or weakness in relation to the decrease in blood pressure may occur in certain patients. If affected, your ability to drive or to operate machinery may be impaired.

bi Preterax 5mg/1.25mg contains lactose monohydrate.

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

bi Preterax 5mg/1.25mg contains sodium

bi Preterax 5mg/1.25mg contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take bi Preterax 5mg/1.25mg

Always take this medicine exactly as your doctor or pharmacist 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. Take your tablet preferably in the morning and before a meal. Swallow the tablet with a glass of water.

If you take more bi Preterax 5mg/1.25mg than you should

If you take too many tablets, contact your doctor or nearest hospital casualty immediately. The most likely effect in case of overdose is low blood pressure. If marked low blood pressure occurs (associated with nausea, vomiting, cramps, dizziness, sleepiness, mental confusion, changes in the amount of urine produced by kidneys), lying down with the legs raised can help.

If you forget to take bi Preterax 5mg/1.25mg

It is important to take your medicine every day as regular treatment is more effective. However, If you forget to take a dose of bi Preterax 5mg/1.25mg, 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 bi Preterax 5mg/1.25mg

As the treatment for high blood pressure 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 the medicinal product and see a doctor immediately, if you experience any of the following side effects that can be serious:

- Severe dizziness or fainting due to low blood pressure (Common - may affect up to 1 in 10 people),
- Bronchospasm (tightening of the chest, wheezing and shortness of breath (Uncommon) (may affect up to 1 in 100 people),
- Swelling of the face, lips, mouth, tongue or throat, difficulty in breathing (angioedema) (See section 2 “Warning and precaution”), (Uncommon) (may affect up to 1 in 100 people),
- 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 (Very rare) (may affect up to 1 in 10,000 people),
- Cardiovascular disorders (irregular heart beat, angina pectoris (pains to the chest, jaw and back, brought on by physical effort), 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),
- 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),
- Life-threatening irregular beat (Not known),
- Disease of the brain caused by liver illness (Hepatic encephalopathy) (Not known).

In decreasing order of frequency, side effects can include:

- Common (may affect up to 1 in 10 people):
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), 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), cramps, feeling of tiredness,
- Uncommon (may affect up to 1 in 100 people):
Mood swings, sleep disturbances, , urticaria, purpura (red pinpoint on skin), blister cluster, 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, fainting, 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, oedema peripheral, fever, increased blood urea, increased blood creatinine, fall.
- Rare (may affect up to 1 in 1000 people):
Psoriasis worsening, changes in laboratory parameters: increased level of liver enzymes, high level of serum bilirubin, fatigue.
- 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), 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.
- Not known (frequency cannot be estimated from the available data): 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), vision blurred, visual impairment, discoloration, numbness and pain in fingers or toes (Raynaud's phenomenon). If you suffer from systemic lupus erythematosus (a type of collagen disease), this might get worse.

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.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store bi Preterax 5mg/1.25mg

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

Keep the container tightly closed in order to protect from moisture.

Store below 30°C.

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 bi Preterax 5mg/1.25mg contains

- The active substances are perindopril arginine and indapamide. One film-coated tablet contains 5mg perindopril arginine (corresponding to 3.395 mg perindopril) and 1.25 mg indapamide.
- The other ingredients in the tablet core are: lactose monohydrate, magnesium stearate (E470B), maltodextrin, anhydrous colloidal silica (E551), sodium starch glycolate (type A), and in the tablet film-coating: glycerol (E422), hypromellose (E464), macrogol 6000, magnesium stearate (E470B), titanium dioxide (E171).

What bi Preterax 5mg/1.25mg looks like and contents of the pack

bi Preterax 5mg/1.25mg tablets are white, rod-shaped film-coated tablets. One film-coated tablet contains 5 mg perindopril arginine and 1.25 mg indapamide.

The tablets are available in containers of 10 or 30 tablets.

Not all pack sizes may be available.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

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Manufacturer:

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