PACKAGE LEAFLET: INFORMATION FOR THE USER

PRETERAX 2.5mg/0.625mg film-coated tablets
perindopril arginine/indapamide

Read all of this leaflet carefully before you start taking this medicine.
- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

In this leaflet:

1. WHAT PRETERAX 2.5mg/0.625mg IS AND WHAT IT IS USED FOR

What is PRETERAX 2.5mg/0.625mg ?
PRETERAX 2.5mg/0.625mg 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).

What is PRETERAX 2.5mg/0.625mg 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 ingredients reduces blood pressure and they work together to control your blood pressure.

2. BEFORE YOU TAKE PRETERAX 2.5mg/0.625mg

Do not take PRETERAX 2.5mg/0.625mg
- 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 PRETERAX 2.5mg/0.625mg,
- 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 or if you are receiving dialysis,
- if you have low or high 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 PRETERAX 2.5mg/0.625mg in early pregnancy - see “Pregnancy and Breast-feeding”),
- if you are breastfeeding.

Take special care with PRETERAX 2.5mg/0.625mg

If any of the following apply to you please talk to your doctor before taking PRETERAX 2.5mg/0.625mg:
- 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 any other heart problems or problems with your kidneys,
- 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 diuretics (spironolactone, triamterene) as their use with PRETERAX 2.5mg/0.625mg should be avoided (see "Taking other medicines"),
- 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 PRETERAX 2.5mg/0.625mg".

You must tell your doctor if you think that you are (or might become) pregnant. PRETERAX 2.5mg/0.625mg 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 PRETERAX 2.5mg/0.625mg, 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)

Athletes should be aware that PRETERAX 2.5mg/0.625mg contains an active ingredient (indapamide) which may give a positive reaction in drug tests.

PRETERAX 2.5mg/0.625mg should not be given to children.

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.

You should avoid PRETERAX 2.5mg/0.625mg with:
- lithium (used to treat depression),
- potassium-sparing diuretics (spironolactone, triamterene), potassium salts.

Treatment with PRETERAX 2.5mg/0.625mg 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 PRETERAX 2.5mg/0.625mg" and "Take special care with PRETERAX 2.5mg/0.625mg"),
- procainamide (for the treatment of an irregular heart beat),

- allopurinol (for the treatment of gout),
- 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),
- medicines for the treatment of cancer,
- erythromycin by injection (an antibiotic),
- halofantrine (used to treat certain types of malaria),
- pentamidine (used to treat pneumonia),
- injectable gold (used to treat rhumatoid polyarthritis),
- vincamine (used to treat symptomatic cognitive disorders in elderly including memory loss),
- bepridil (used to treat angina pectoris),
- sultopride (for the treatment of psychoses),
- medicines used for heart rhythm problems (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol),
- 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 mental disorders such as depression, anxiety, schizophrenia…(e.g. tricyclic antidepressants, neuroleptics),
- tetracosactide (to treat Crohn's disease).

Taking PRETERAX 2.5mg/0.625mg with food and drink
It is preferable to take PRETERAX 2.5mg/0.625mg before a meal.

Pregnancy and breast-feeding

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 PRETERAX 2.5mg/0.625mg before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of PRETERAX 2.5mg/0.625mg. PRETERAX 2.5mg/0.625mg 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 PRETERAX 2.5mg/0.625mg 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
PRETERAX 2.5mg/0.625mg 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.

Important information about some of the ingredients of PRETERAX 2.5mg/0.625mg
PRETERAX 2.5mg/0.625mg 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 PRETERAX 2.5mg/0.625mg

Always take PRETERAX 2.5mg/0.625mg exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual dose is one tablet once a day. Your doctor may decide to increase the dose to 2 tablets daily or 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.

The score line is not intended for breaking the tablet.

If you take more PRETERAX 2.5mg/0.625mg 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 such as dizziness or faintness), lying down with the legs raised can help.

If you forget to take PRETERAX 2.5mg/0.625mg
It is important to take your medicine every day as regular treatment is more effective. However, If you forget to take a dose of PRETERAX 2.5mg/0.625mg, 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 PRETERAX 2.5mg/0.625mg
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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, PRETERAX 2.5mg/0.625mg can cause side effects, although not everybody gets them.
If you experience any of the following, stop taking the medicinal product at once and tell your doctor immediately :

- swelling of the face, lips, mouth, tongue or throat, difficulty in breathing,
- severe dizziness or fainting,
- unusual fast or irregular heart beat.

In decreasing order of frequency, side effects can include:

- Common (occur in fewer than 1 in 10 users but in more than 1 in 100 users): headache, feelings of dizziness, vertigo, pins and needles, vision disturbances, tinnitus (sensation of noises in the ears), light-headedness due to low blood pressure, cough, shortness of breath, gastro-intestinal disorders (nausea, epigastric pain, anorexia, vomiting, abdominal pain, taste disturbances, dry mouth, dyspepsia or difficulty of digestion, diarrhoea, constipation), allergic reactions (such as skin rashes, itching), cramps, feeling of tiredness,
- Uncommon (occur in fewer than 1 in 100 users but in more than 1 in 1000 users): mood swings, sleep disturbances, bronchospasm (tightening of the chest, wheezing and shortness of breath), angioedema (symptoms such as wheezing, swelling of the face or tongue), urticaria, purpura (red pinpoints on skin), kidney problems, impotence, sweating,
- Very rare (occur in fewer than 1 in 10,000 users): confusion, cardiovascular disorders (irregular heart beat, angina, heart attack), eosinophilic pneumonia (a rare type of pneumonia), rhinitis (blocked up or runny nose), severe skin manifestations such as erythema multiforme. If you suffer from systemic lupus erythematosus (a type of collagen disease), this might get worse. Cases of photosensitivity reactions (change in skin appearance) after exposure to the sun or artificial UVA have also been reported.
- Not known (frequency cannot be estimated from the available data): fainting, life-threatening irregular beat (Torsade de Pointes), abnormal ECG heart tracing, increased levels of liver enzymes.

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

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.

5. HOW TO STORE PRETERAX 2.5mg/0.625mg

Keep out of the reach and sight of children.

Do not use PRETERAX 2.5mg/0.625mg 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.

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.

6. FURTHER INFORMATION

What PRETERAX 2.5mg/0.625mg contains

- The active substances are perindopril arginine and indapamide. One film-coated tablet contains 2.5 mg perindopril arginine (corresponding to 1.6975 mg perindopril) and 0.625mg 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 PRETERAX 2.5mg/0.625mg looks like and contents of the pack

PRETERAX 2.5mg/0.625mg tablets are white, rod-shaped film-coated tablets with an embossed line on both faces. One film-coated tablet contains 2.5 mg perindopril arginine and 0.625 mg indapamide.
The tablets are available in containers of 14, 20, 28, 30, 50, 56, 60, 90, 100 or 500 tablets.
Not all pack sizes may be available.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder :
For RMS (France):
Les Laboratoires Servier
50, rue Carnot
92284 Suresnes cedex - France

Manufacturer:
Les Laboratoires Servier Industrie
905 route de Saran
45520 Gidy - France

and

Servier (Ireland) Industries Ltd

Gorey Road
Arklow - Co. Wicklow – Ireland

and

ANPHARM Przedsiębiorstwo Farmaceutyczne S.A.
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This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	PRETERAX-ARGININ
Belgium	PRETERAX 2,5 mg/0,625 mg
Cyprus	COVERSYL PLUS ARGININE 2.5 mg/0.625 mg
Czech Republic	NOLIPREL NEO
Estonia	NOLIPREL ARGININE
Finland	PRETERAX NOVUM
France	PRETERAX 2,5mg/0,625mg
Germany	PRETERAX N 2,5 mg/ 0,625 mg Filmtabletten
Greece	PRETERAX 2,5 mg/0,625 mg
Hungary	NOLIPREL ARGININ
Ireland	COVERSYL ARGININE PLUS 2.5mg/0.625mg
Italy	PRETERAX 2,5 mg/0,625 mg
Latvia	NOLIPREL ARGININE 2.5mg/0.625mg apvalkotās tabletes
Lithuania	NOLIPREL 2,5 mg/0,625 mg tabletės
Luxembourg	PRETERAX 2,5 mg/0,625 mg
Malta	PRETERAX ARGININE 2.5mg/0.625mg
The Netherlands	PRETERIAN 2,5 mg/0,625 mg
Poland	NOLIPREL (2.5/0.625)
Portugal	PRETERAX 2,5 mg/0,625 mg
Romania	NOLIPREL ARG 2,5 mg/ 0,625 mg
Slovakia	NOLIPREL A
Slovenia	BIONOLIPREL 2.5mg/0.625mg filmsko obložene tablete
United Kingdom	COVERSYL ARGININE PLUS 2.5 mg / 0.625 mg

This leaflet was last approved in {MM/YYYY}.