

PACKAGE LEAFLET: INFORMATION FOR THE USER

Perindopril tert-butylamine / Indapamide Glenmark 2mg/0.625mg and 4mg/1.25mg Tablets

Perindopril tert-butylamine 2mg / Indapamide 0.625mg
Perindopril tert-butylamine 4mg / Indapamide 1.25mg

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.

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1. WHAT PERINDOPRIL TERT-BUTYLAMINE / INDAPAMIDE GLENMARK TABLETS IS AND WHAT IT IS USED FOR

Perindopril tert-butylamine / Indapamide Glenmark Tablets is a combination of Perindopril and Indapamide. They belong to a group of anti-hypertensive medicines, which are used in the treatment of high blood pressure.

Perindopril belongs to a class of ACE inhibitors. These work by widening the blood vessels in your body, which make it easier for your heart to pump blood around through them.

Indapamide belongs to a group of medicines called diuretics. These work by allowing your kidneys to produce more urine than normal.

Each of the individual medicines work together to lower your blood pressure and control it.

2. BEFORE YOU TAKE PERINDOPRIL TERT-BUTYLAMINE / INDAPAMIDE GLENMARK TABLETS

Do not take Perindopril tert-butylamine / Indapamide Glenmark Tablets

- If you are allergic (hypersensitive) to Perindopril or Indapamide or any of the other ingredients of Perindopril tert-butylamine / Indapamide Glenmark Tablets.
- If you are allergic to any other ACE inhibitors or diuretics (Sulphonamides).
- If you have experienced swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, with previous ACE inhibitor therapy. This is a condition called angioneurotic oedema (Quincke’s oedema)
Alternatively, if you or any of your family members have had these symptoms tell your doctor as soon as possible.
- If you have heart problems or are on medication (See “Taking other medicines”)
- If you are more than 3 months pregnant. (It is also better to avoid Perindopril tert-butylamine / Indapamide Glenmark Tablets in early pregnancy see pregnancy section.)
- If you are breastfeeding
- If you have kidney failure or are receiving dialysis
- If you have serious liver disease or suffer from a condition called hepatic encephalopathy (which is brain and nervous system impairment caused by severe liver disease)
- If your doctor has told you, that you have low or high blood potassium.

Take special care with Perindopril tert-butylamine / Indapamide Glenmark Tablets

Tell your doctor before you start to take this medicine:

- If you have bilateral renal artery stenosis (narrowing of the main blood vessel leading to the kidney) or a single functioning kidney
- If you have diabetes
- If you are on a low salt diet or use salt substitutes, which contain potassium
- If you take lithium or potassium-sparing diuretics (e.g. Spironolactone, Triamterene)
- If you are taking a medicine which is a combination with a potassium-sparing diuretic
- If you are going to have an operation under general anaesthetic, as you may need to stop treatment a few days beforehand.
- If you have Atherosclerosis (a disease of the arteries in which blood vessel walls thicken and harden due to cholesterol deposit)
- 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 (e.g. bee or wasp sting)
- If you are to undergo a medical test that requires injection of a substance that makes organs like the kidney or stomach visible on an x-ray (iodinated contrast agent)
- if you have anaemia (a condition when the red blood cells in your body carry less oxygen, some of the symptoms of anaemia include tiredness, headaches, dizziness)
- If you have Gout (a disease where uric acid crystals cause swollen joints)
- If you have a collagen disease such as systemic lupus erythematosus or scleroderma.
- You must tell your doctor if you think you are (or might

become) pregnant. Perindopril tert-butylamine / Indapamide Glenmark Tablets is not recommended in early pregnancy, and must not be taken when you are more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

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 Perindopril tert-butylamine / Indapamide Glenmark Tablets with:

- Lithium
- Potassium-sparing diuretics (e.g. spironolactone, triamterene alone or in combination), potassium salts
- Allopurinol (treatment of gout)
- Procainamide (treatment of irregular heartbeat)
- Systemic corticosteroids (used to treat various conditions including severe asthma and rheumatoid arthritis)
- Other medicines to treat high blood pressure
- immunosuppressants used for the treatment of auto immune disorders or following transplant surgery to prevent rejection (e.g Ciclosporin)

Treatment with Perindopril tert-butylamine / Indapamide Glenmark Tablets can be affected by other medicines. Tell your doctor if you are taking any of the following medicines as special care may be required:

- Astemizole or Terfenadine (antihistamines for hayfever or allergies)
- Bepridil (used to treat angina pectoris - an uncomfortable feeling in this chest)
- Erythromycin by injection, Moxifloxacin, Sparfloxacin (antibiotics)
- Halofantrine (used to treat certain types of malaria)
- Pentamidine (used to treat pneumonia which is a serious lung infection)
- Vincamine (used to treat disorders of the brain in elderly)
- Baclofen (to treat muscle stiffness occurring in diseases such as multiple sclerosis)
- Medicines to treat diabetes such as insulin, Metformin or hypoglycaemic sulphonamides
- Non-Steroidal anti-inflammatory drugs (e.g. Ibuprofen) or high dose salicylates (e.g. Aspirin)
- Potassium lowering drugs e.g. Amphotericin B (by injection to treat severe fungal disease), glucocorticoids and mineralocorticoids (systemic route), or stimulant laxatives (e.g. Senna)
- Potassium-sparing diuretics (amiloride, spironolactone, triamterene)
- Thiazide or loop diuretics
- Medicines to treat irregular heart beat such as Quinidine, Hydroquinidine, Disopyramide, Amiodarone, Bretylium, Dofetilide, Ibutilide and Sotalol.
- Medicines to treat mental disorders such as depression, anxiety, schizophrenia (e.g. tricyclic antidepressants, neuroleptics such as Chlorpromazine, Cyamemazine, Levomepromazine, Thioridazine, Trifluoperazine, Amisulpiride, Tiapride, Droperidol, Haloperidol, Pimozide)
- Cisapride, Diphemanil, Mizolastine
- Methadone
- Sultopride (used in the treatment of psychotic disorders)
- Tetracosactide (used to treat Crohn’s disease)
- calcium salts

Taking Perindopril tert-butylamine / Indapamide Glenmark Tablets with food and drink

It is recommended that Perindopril tert-butylamine / Indapamide Glenmark Tablets are taken in the morning on an empty stomach. Swallow the tablets with a glass of water.

Pregnancy and breast-feeding

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Perindopril tert-butylamine / Indapamide Glenmark Tablets before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Perindopril tert-butylamine / Indapamide Glenmark Tablets. Perindopril tert-butylamine / Indapamide Glenmark Tablets is not recommended in early pregnancy, and must not be taken when you are 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. Perindopril tert-butylamine / Indapamide Glenmark Tablets should not be taken by 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.

GLENMARK GENERICS LTD.		DATE: 07.04.2014	PANTONE SHADE NO: 1 (Black)	
PRODUCT NAME: Perindopril/Indapamide 2/1.25mg Insert-From		PKG. DEV.:	Item code, Version, Consistency of Design, overprint area, Pack size, Dimensions & Layout	
ITEM CODE: XXXXXX VERSION: XXXXX				
PHARMACODE: _____		RA	Regulatory Text	
COUNTRY: Ireland		QA:	Entire Text	
LOCATION: Goa		PRODUCTION:	Machine Suitability	
PACK : 180 x 38 mm		REMARKS:		
ACTUAL SIZE: 180 x 450 mm				
SPECIFICATION: 40 gsm Bible Paper				

