

BEPELIX TABLET 2.5MG

Indapamide 2.5mg

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What *Bepelix* is used for

For treatment of hypertension, alone or in combination with other antihypertensive drugs.

How *Bepelix* work

Indapamide, a diuretic which inhibits reabsorption of water and electrolytes, primarily as a result of action on the cortical diluting segment of the kidneys. It is also blood pressure lowering agent. Its mechanism of action is not clearly understood but thought to involve both kidneys and other than kidney. The diuretic effect (reduction of fluid and blood volume) probably contributes only minimally since indapamide reduces blood pressure at a dose well below the effective diuretic dose. The blood pressure lowering effect is thought to be the result of reduction in the resistance of blood vessels of hands and feet.

Before you use *Bepelix*

When you must not take it

If you are hypersensitive to indapamide/other sulphonamide derived agents, severe renal/hepatic impairment, recent cerebrovascular accident, anuria & stroke.

Before you start to take it

Serum uric acid concentration increased in indapamide therapy within normal limits. This level should be monitored at start of therapy and at periodic intervals. It is used with caution in cases of overactive thyroid glands which cause increased appetite, weight loss or sweating as iodine bound to blood protein decreased. Cautiously used in kidney failure, gout & blood potassium levels be monitored. Use cautiously in elderly

as they are sensitive to low blood pressure and electrolyte effects. Adequate and well-controlled studies not done on pediatrics.

Indapamide is unlikely to impair a patient's ability to drive or use machinery.

Taking other medications

Lithium-toxicity because of reduced renal clearance. Sympathomimetics-antihypertensive effects reduced as arterial responsiveness to adrenaline reduced. Neuromuscular blocking agents-hypokalemia & enhance blockade of non-depolarizing effects. Glucocorticoids & mineralocorticoids-decrease the natriuretic & diuretic effects & intensify electrolyte imbalance.

Amiodarone-increased risk of arrhythmias associated with hypokalemia. Digitalis glycosides-enhance the possibility of digitalis toxicity. NSAIDs-inhibit vasodilator prostaglandins which results in acute renal insufficiency in dehydrated patients. Diuretics(amiloride, canrenone, spironolactone, triamterene)-may cause hypokalemia/hyperkalemia in patients with renal failure/diabetes.

How to take *Bepelix*

How much to take

2.5 mg daily. Action of indapamide is progressive & reduction blood pressure continue and not reach a max. until several months after start of therapy. A larger dose than 2.5mg is not recommended as there is no appreciable antihypertensive effect but a diuretic effect, may be apparent. Elderly patients are more sensitive to effects of usual dose. Dosage adjustments based on serum electrolyte conc. & renal function prior to initiation of therapy & periodic intervals.

When to take it

Take indapamide in the morning or exactly as your doctor has told you.

How long to take it

You should check with your doctor or pharmacist.

If you forget to take it

Do not take a double dose to make up for a forgotten tablet.

If you take too much (overdose)

Overdosage will cause nausea, vomiting, weakness, GI disorders & electrolyte disturbances. Severely, it will

cause hypotension & depressed respiration. If overdose, see doctor immediately if symptoms exist.

While you are using *Bepelix*

Things you must do

Inform doctor of medications you are taking.

Things you must not do

You must take your medication as directed.

Things to be careful of

If you are pregnant or become pregnant or breast-feeding during treatment, you should not take indapamide unless your doctor tells you to. This is because the risk to your unborn baby is not yet known.

Side effects

Electrolyte imbalance includes dry mouth, increased thirst, irregular heartbeat, mood/mental changes, muscle cramps/pains, nausea, vomiting, weakness and weak pulse. Electrolyte imbalance(low sodium in blood, low acid in blood, low hydrogen ion in blood, low blood levels of potassium which causes muscle weakness, twitching or abnormal heart rhythm) which occurs is dose related but rarely symptomatic. Headache, dizziness, fatigue, loss or appetite, diarrhea, constipation and indigestion occur. Allergic reactions such as skin rash, itching or hives may also occur.

After using *Bepelix*

Storage

Store in cool, dry place below 30°C. Protect from light. Keep out of reach of children.

Disposal

Do not dispose via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

Product description

What it looks like

Red, round, biconvex, non-scored, film-coated tablet.

Ingredients

Cornstarch, lactose monohydrate, polyvinylpyrrolidone, magnesium stearate hydroxypropyl methylcellulose, talc and titanium dioxide.

MAL NO: MAL19991433A

Manufacturer

Prime Pharmaceutical Sdn. Bhd.

1505, Lorong Perusahaan Utama 1

Taman Perindustrian Bukit Tengah

14000 Bukit Mertajam, Penang, Malaysia.

Date of revision

27-10-2011

Marketing Authorization Holder

Prime Pharmaceutical Sdn. Bhd.

Penang, Malaysia.

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Indapamide 2.5mg

Apakah yang ada pada risalah ini

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Apakah kegunaan *Bepelix*

Untuk penyakit darah tinggi; rawatan tunggal atau kombinasi dengan ubat penyakit darah tinggi yang lain.

Bagaimana *Bepelix* berfungsi

Indapamide, ubat diuretik merencat serapan semula air dan elektrolit, terutama daripada tindakan ke atas segmen tubul distal ginjal. Ia adalah agen penurun tekanan darah juga. Cara tindakannya tidak jelas tetapi mungkin melibatkan ginjal dan luar ginjal. Kesan diuretik (pengurangan bendarir luar sel dan darah) adalah minima kerana ia mengurangkan tekanan darah pada dos kurang daripada dos berkesan ubat diuretik. Kesan penurunan tekanan darah mungkin disebabkan pengurangan rintangan saluran darah pinggiran.

Sebelum mengambil *Bepelix*

Bila tidak boleh mengambil
Jikalau hipersensitif kepada indapamide /agen sulfonamid lain, ketidaksempurnaan serius ginjal dan hati, kemalangan cerebrovaskular baru, anuria dan strok.

Sebelum mula mengambil

Kepekatan asid urik serum meningkat dengan terapi indapamide normal. Paras urate perlu dimonitor pada permulaan terapi dan berkala. Ubat perlu digunakan dengan berhati-hati dalam kes kelenjar tiroid aktif yang menyebabkan selera makan meningkat, penurunan berat badan atau perpeluhuan kerana iodin terikat protein darah berkurangan. Perlu berhati-hati dalam penggunaan kegagalan ginjal, gout dan paras potassium darah dimonitor, pesakit tua kerana kesensitifan kepada tekanan darah rendah dan kesan elektrolit. Kajian menyeluruh dan terkawal tidak dilanjkan ke atas golongan kanak-kanak. Indapamide sepatutnya tidak

mengganggu keupayaan memandu dan mengendalikan mesin.

Jika mengambil ubat-ubat lain
Keracunan litium akibat pengurangan pelupusan ginjal. Simpatomimetik-kesan antihipertensif berkurangan akibat pengurangan gerakbalas arteri kepada adrenalin. Agen penghalang otot saraf-hipokalemia dan peningkatan halangan kesan bukan-nyahkutub. Glukokortikoid & mineralokortikoid-pengurangan kesan natriuretic & diuretic dan peningkatan ketidakseimbangan elektrolit.

Amiodarone-peningkatan risiko aritmia berkaitan dengan hipokalemia. Digitalis glikosid-kemungkinan peningkatan keracunan digitalis. NSAID-merencat kesan prostaglandin vasodilator dan mengakibatkan kelemahan ginjal akut dalam pesakit yang mengalami dehidrasi. Diuretik (amiloride, canrenone, spironolakton, triamterene)-mungkin menyebabkan hipokalemia/hiperkalemia pesakit kegagalan ginjal atau kencing manis.

Cara menggunakan *Bepelix*

Berapa banyak harus diambil
2.5 mg setiap hari. Kesan indapamide adalah progresif dan penurunan tekanan darah berlanjutan sehingga ke maksimum dalam tempoh beberapa bulan dari permulaan rawatan. Dos lebih daripada 2.5mg tidak digalakkan kerana tiada lebihan kesan antihipertensif tetapi kesan diuretik sahaja berlaku. Pesakit tua lebih sensitif kepada kesan dos biasa. Pengubabsuaian dos adalah berdasarkan kepada kepekatan elektrolit serum dan fungsi ginjal sebelum memulakan rawatan dan pemonitoran berkala.

Bila perlu diambil

Ambil indapamide pada waktu pagi atau mengikut arahan oleh doktor.

Berapa lama perlu diambil

Perlu mengikut nasihat doktor atau ahli farmasi.

Jika terlupa mengambil

Jangan mengambil dos berganda sebagai gantian dos yang terlepas.

Jika mengambil berlebihan(terlebih dos)

Terlebih dos menyebabkan rasa loya, muntah, kelemahan, gangguan gastrousus dan elektrolit. Keadaan serius, ia menyebabkan hipotensi dan penekanan respirasi. Perlu dapatkan rawatan segera doktor jikalau terdapat tanda-tanda terlebih dos.

Semasa menggunakan *Bepelix*

Perkara yang perlu dilakukan
Beritahu doktor ubat yang sedang diambil.

Perkara yang tidak boleh dilakukan
Pengambilan ubat mestilah seperti yang diarahkan.

Perkara yang perlu diberi perhatian
Beritahu doktor jikalau hamil atau penyusuan semasa rawatan, indapamide tidak boleh diambil tanpa arahan doktor. Ini adalah kerana tiada maklumat mengenai risiko kepada bayi dalam kandungan.

Kesan-kesan sampingan

Ketidakseimbangan elektrolit merangkumi mulut kering, dahaga, denyutan jantung tak teratur, perubahan mental, kekejangan/sakit otot, loya, muntah, kelemahan dan nadi lemah. Ketidakseimbangan elektrolit(paras natrium, asid dan hidrogen dan kalium darah rendah) yang hadir adalah bergantung kepada dos dan jarang bertanda. Sakit kepala, pening, keletihan, tiada selera makan, cirit-birit, sembelit dan ketidak penghadaman juga berlaku. Reaksi alergi seperti ruam kulit, gatal-gatal mungkin juga berlaku.

Cara penyimpanan dan pelupusan *Bepelix*

Penyimpanan

Simpan di tempat yang dingin dan kering, bawah 30°C. Jauhkan dari cahaya. Jauhkan dari kanak-kanak

Pelupusan

Jangan dibuang dalam air sisa atau sisa buangan. Dapatkan nasihat ahli farmasi cara pelupusan ubat yang ingin dibuang.

Maklumat lanjut

Rupa dan warna produk
Tablet merah bersalut, bulat, biconveks, tanpa skor.

Bahan-bahan kandungan
tepung jagung, laktos monohidrat, polivinilpirolidon, magnesium stearat, hidroksipropil metilselulos, talkum dan titanium dioxide.

MAL NO: MAL19991433A

Pengilang

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Pemegang pendaftaran keluaran

Prime Pharmaceutical Sdn. Bhd.
Pulau Pinang, Malaysia.

Tarikh kemaskini RiMUP

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