INSTRUCTION

FOR MEDICAL USE OF MEDICAL PRODUCT

BLEMAREN®

Registration number: ЛСР-001331-07

Trade name: Blemaren®

Group name: Potassium hydrogen carbonate + Citric acid + Sodium citrate

Dosage form: effervescent tablets

Composition:

1 effervescent tablet contains:

Active substances: citric acid anhydrous – 1197.0 mg, potassium hydrogen carbonate – 967.5 mg, sodium citrate anhydrous – 835.5 mg;

excipients: lactose monohydrate - 115.0 mg, mannitol - 105.0 mg, adipinic acid - 35.0 mg, macrogol 6000 (polyethylene glycol 6000) - 100.0 mg, sodium saccharinate (saccharin sodium) - 10.0 mg, lemon flavor - 35.0 mg.

Description

Round flat faced white tablets, with countersink, with weak taste of lemon.

Pharmacotherapeutic group: nefrourolitiaz curative agent.

ATC code: G04BC

Pharmacological properties

During dissolution of Blemaren® effervescent tablets in water potassium-sodium hydrogen citrate and carbon dioxide is formed. While using medical product rising of parameter urine pH takes place. So, product dissolves and prevents formation of uric acid stones. Besides, it potentiates excretion of citrates and lowers excretion of calcium, enhances solubility of calcium oxalate in urine, inhibits formation of crystals and, therefore, inhibits formation of calcium-oxalate stones.

Pharmacokinetics

Bioavailability - about 100 %. After one-day use of medical product Blemaren® applied quantity of sodium and potassium is excreted from organism by kidneys for 24 – 48 hr. In case of continuous use of medical product daily excretion of potassium and sodium corresponds to daily consumption. In blood or in blood plasma there are no significant changes of gas parameters in blood or electrolytes. This means that due to renal regulation of alkalization acid-alkaline

balance in body is maintained, and accumulation of sodium and potassium during normal functioning of kidney does not take place.

Indications for use

- dissolution of uric acid and calcium-oxalate stones in urinary tracts and prevention of their formation;
- dissolution of mixed urine acid-oxalate stones (in case of oxalates content less than 25 %);
- alkalization of urine in persons, who receive cytostatics or medical products that elevate excretion of uric acid; during treatment of patients with cystic stones;
- symptomatic treatment of skin porphyria.

Contraindications

- hypersensitivity;
- lactase deficiency, lactose intolerance, glucose-galactose malabsorption;
- acute and chronic renal insufficiency;
- metabolic alkalosis;
- urinary tract infections, caused by microorganisms that split urea;
- episodic inherited adynamia;
- need to keep strict low-sault diet (for example, in case of severe types of arterial hypertension);
- children below 12 years (since there is not enough clinical experience relating this age group).

Administration during pregnancy and breast-feeding period

There are no confirmed data of adverse effects of medical product Blemaren® during pregnancy and breast-feeding period. Administration of medical product is possible after consulting to a doctor.

Posology and method of administration

Before oral use dissolve tablets in 200 mL of liquid (water, tea, fruit juices or alkaline mineral water). Presence of small turbidity and small quantity of undissolved particles on a surface is possible.

Daily dose - 2 - 6 tablets.

Daily dose is uniformly separated into 3 equal parts and is administrated after meals within a day. Control of efficacy of medical product is performed by determination of pH of fresh urine 3 times a day before regular use of medical product with the help of indicator paper, which is placed into each pack. Indicator area of test band should be inserted into urine for 5 – 10 sec, than taken out and in 2 min compare obtained color of test band with color scale, applied to indicator bands kit. Record obtained pH value in control calendar, which is inserted into pack. Based on obtained data individual dosage with goal of effective therapy is determined.

Dose is considered as correctly chosen in case if pH is within recommended limits for each parameter within a day. For dissolution *of uric acid stones* urine pH should be within 7.0 – 7.2. For dissolution of *uric-oxalate* mixed stones and prevention of formation of *calcium-oxalate* stones urine pH should be maintained at the level of 6.8 – 7.4. For alkalization of urine in patients with *cystic stones* urine pH should be at the range 7.5 – 8.5. For treatment of *porphyria* urine pH should be at the range 7.2 – 7.5. During treatment by *cytostatics* urine pH should be not less than 7.0. In case if pH value is below stated, dose should be elevated, in case if it is above - lower. Duration of treatment is not less than 4 - 6 months.

In case of presence of cystic stones and treatment of porphyria for efficacy control special indicator paper should be used for determination of pH at the range 7.2 – 9.7 (is not present in the kit).

Side effects

According to World health organization (WHO) adverse events are classified in accordance with frequency of their development in the following way: very frequent (≥ 1/10), frequent (≥ 1/100, <1/10), non-frequent (≥ 1/1000, <1/100), rare (≥ 1/10000, <1/1000) and very rare (< 1/10000); frequency unknown (frequency of appearance of events cannot be determined based on present data).

In case of individual intolerability of components of medical product *allergic reactions* are possible.

From gastro-intestinal tract:

frequent - abdominal pain, nausea, vomiting, diarrhea.

From metabolism and nutrition:

frequency unknown - edemas (retention of sodium), metabolic alkalosis.

Overdosage

In case of normal kidney functioning adverse influence of medical product onto the change of physiological parameters of metabolism is noted neither at any recommended dose, nor at higher dose, since excretion of extra alkaline by kidneys is a natural way of regulation acid-alkaline balance in body.

Upper limit of above stated parameter urine pH should not be exceeded for several days, since because of exceeding of parameter pH (pH > 7.8) there is elevated risk of phosphates crystallization.

Possible overdosage may be corrected by lowering of medical product dose. In case of need measures for treatment of metabolic alkalosis may be taken.

Drug-to-drug interaction

Simultaneous use of medical products, that contain citrates and aluminum, may lead to elevation of absorption of aluminum. Range between administration of such products should be not less than 2 hr. Effect of cardiac glycosides may be less, in case if their simultaneous use together with Blemaren® product, because of presence of potassium in medical product.

Several medicines, that lower arterial pressure (aldosterone antagonists, potassium-sparing diuretics, inhibitors of angiotensin transforming enzyme, sartans), and antiinflammatory non-steroid agents and analgesics may lower potassium excretion.

Special warnings

Average daily dose (4 effervescent tablets) contains about 1.5 mg of potassium and 0.9 gm of sodium (should be noted in patients with limitations of consumption of sodium chloride).

May be used in case of chronic renal failure, which is not accompanied with retention of potassium ions.

May be prescribed for patients with diabetes mellitus.

During dissolving uric acid stones avoid multi-day excessive alkalization of urine, since at rising of pH above 7.8 appearance of precipitate of phosphate salts on the surface of uric acid stones is possible, that may lead to their further dissolution.

During treatment consumption of high-protein and purine basis-rich products should be limited, and enough consumption of water should be provided (not less than 1.5 - 2 L).

Effects on ability to drive and use machines

Medical product does not influence ability to drive and use machines, that require increased attention.

Dosage form

Effervescent tablets.

20 tablets into plastic polypropylene tube, sealed with plastic stopper with drying agent. 4 tubes together with indicator paper, control calendar and instruction for use are placed into carton box.

Storage conditions

Store at the temperature not more than 25 °C.

Keep out of reach of children!

After opening avoid moisture ingress!

Shelf life

4 years.

Do not use after expiration of shelf-life.

Prescription status

OTC.

MA Holder:

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Manufacturer:

Laboratorios Medicamentos Internacionales, S.A.,

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