1. NAME OF THE MEDICINAL PRODUCT

Jawalk Solution

(Potassium Citrate & Citric Acid Oral Solution USP)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:

Potassium Citrate Monohydrate USP….....1100 mg

Citric Acid Monohydrate USP…..... 334 mg

Flavoured syrupy base.....Q.S.

3. PHARMACEUTICAL FORM

Oral dosage Form: Solution

A clear orange coloured syrup with a pleasant raspberry flavour packed in a 200 ml round amber coloured glass bottle USP type-III with 28 mm printed pp caps.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Jawalk Solution is used for the symptomatic relief of dysuria associated with mild urinary tract infections, especially cystitis.

4.2 Posology and method of administration

Oral:

Recommended Doses

Unless directed otherwise by a doctor:

Adults including the elderly, and children over 6 years: 10ml.

Children 1 - 6 years: 5ml.

It should be taken well diluted with water, after meals.

Shake the bottle before use.

Dosage Schedule

The dose may be taken three times a day.

4.3 Contraindications:

Contraindicated in hyperkalaemia, renal dysfunction, ventricular arrhythmics and Addison's Disease.

4.4 Special warnings and precautions for use:

Potassium Citrate Mixture provides symptomatic relief only and is not anti-bacterial. Effective anti-bacterial therapy should be co-prescribed. It should be used with caution when renal or cardiac dysfunction is present.

Labels to state: if symptoms persist consult your doctor. Discard any unused mixture 2 months after opening.

Use with caution in the elderly

This product contains 1.1g of sucrose per 5ml dose. To be taken into account in people with diabetes. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

This medicine contains 2.5mg sodium benzoate per 5ml dose.

This medicine contains 0.02mg ethanol in each 5ml dose, which is equivalent to 0.46 vol%. The amount in each 5ml dose of this medicine is equivalent to less than 0.46ml beer or 0.18ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

This medicine contains less than 1mmol sodium (23 mg) per 5ml dose, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interaction

Concurrent administration of potassium-containing drugs, potassium sparing diuretics or other drugs that increase potassium levels (e.g. ACE inhibitors, ciclosporin, aliskiren) may lead to hyperkalaemia. May interact with cardiac glycosides. Citrates alkalinise the urine and thus may alter the urinary excretion of a number of drugs. This may lead to increased renal clearance of acidic drugs, such as salicylates, tetracylines

and barbiturates, and prolongation of the half-life of basic drugs, such as sympathomimetics and stimulants. Particularly noteworthy is the diminished anti-bacterial activity of nitrofurantoin and methenamine.

4.6 Fertility, pregnancy and lactation

No adverse effects are anticipated at recommended doses when used for initial symptomatic relief only. Treatment with potassium citrate mixture is adjunctive and secondary to anti-bacterial treatment of urinary tract infection.

4.7 Effects on ability to drive and use machines

No effect on mental alertness.

4.8 Undesirable effects

Mild nausea and occasionally vomiting may occur due to gastric irritation. Other side effects are those due to hyperkalaemia (if this occurs).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions.

4.9 Overdose

Overdosage is accompanied by nausea, vomiting, abdominal pain and symptoms due to hyperkalaemia and metabolic acidosis. Fluid and electrolyte balance together with ECG should be closely monitored.

Treatment is symptomatic and supportive. Moderate to severe hyperkalaemia is a medical emergency requiring prompt correction.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Citrate and citric acid solutions are systematic and urinary alkalinizers thereby providing symptomatic relief of dysuria.

5.2 Pharmacokinetic properties

Potassium Citrate is absorbed and the citrate is metabolised to bicarbonate. Citric acid is metabolised to carbon dioxide and water. Oxidation is virtually complete with less than 5% of citrate being excreted unchanged in the urine.

5.3 Preclinical safety data

None.

6. Pharmaceutical particulars

6.1 List of excipients

Sorbitol

Sodium Saccharin

Methylparaben

Sodium Benzoate

Sunset yellow colour

Raspberry flavour

Purified water

6.2 Incompatibilities

Incompatible with calcium and strontium salts.

6.3 Shelf life

200ml: 36 months unopened

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

200 ml Amber bottle with 28 mm Printed PP Cap.

6.6 Special precautions for disposal and other handling

None.

7. APPLICANT/ MANUFACTURER

JAWA INTERNATIONAL LIMITED

Plot 6 Abimbola Street, Isolo Industrial Estate, Isolo, Lagos, Nigeria

Phone: +2348073894283. E-mail: contactus@jawasil.com