SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Effercitrate Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains potassium bicarbonate and anhydrous citric acid. When dissolved in water, the solution will contain the equivalent of 1.5g potassium citrate and 0.25g citric acid.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

White circular, flat effervescent tablets

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

For the treatment of cystitis, symptoms of cystitis and as an initial therapy in mild symptomatic cystitis prior to an MSU result. Confirmed bacterial infections should then be treated with an appropriate course of an antibacterial agent.

4.2. Posology and Method of Administration

For oral administration.

Adults and Children over 6 years: Two tablets to be dissolved in a glass of water up to three times daily.
Children under 6 years: Not recommended.
Elderly: As adult dose. See section 4.4

Sufficient should be given to render and maintain the urine alkaline

4.3. Contraindications

Contraindicated in hyperkalaemia from any cause, renal dysfunction particularly with oliguria, ventricular arrhythmics, untreated Addison's disease and acute dehydration.
Contraindicated in known hypersensitivity to potassium citrate, citric acid or any of the other ingredients.

4.4. Special warnings and precautions for use

Caution should be observed in patients with kidney disease, hypertension or heart disease.
Use with caution in elderly patients as potassium excretion is reduced increasing the risk of hyperkalaemia.If symptoms persist or worsen after 4 days, patients should seek medical advice.

4.5. Interactions with other medicinal products and other forms of interaction

Potassium salts should not be co-administered with other potassium containing medicines, potassium sparing diuretics (such as amiloride and triamterene), aldosterone antagonists (such as spironolactone) or other medicines that increase potassium levels such as angiotensin-II receptor antagonists, ACE inhibitors, aliskiren, cyclosporine and tacrolimus.
The activity of cardiac glycosides is to some extent dependent upon serum potassium levels, therefore, there is a possible interaction and caution is advised.
In patients with acidosis, the acid-base balance should be monitored.
In patients with hypertension, correction of hypokalaemia may lower blood pressure.
Citrates alkalise the urine and thus may alter the urinary excretion of a number of drugs such as salicylates, tetracyclines and barbiturates, and may also prolong the half-life of basic drugs such as sympathomimetics and stimulants.
The anti-bacterial activity of nitrofurantoin and methenamine is diminished.

4.6. Fertility, pregnancy and lactation

Patients should consult a doctor before taking Effercitrate Tablets in pregnancy or lactation.

4.7. Effects on ability to drive and use machines

No effects known.

4.8. Undesirable effects

Gastric irritation may occur. The tablets should always be well diluted with water. Gastric effects may be minimised by taking with, or after meals.

<u>Reporting of suspected adverse reactions</u>
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 via the Yellow Card Scheme (www.mhra.gov.uk/yellowcard).

4.9. Overdose

Overdose is accompanied by nausea, vomiting, abdominal pain and symptoms due to hyperkalaemia (including paraesthesia of the extremities, listlessness, mental confusion, weakness, paralysis, hypotension, cardiac arrhythmias, heart block and cardiac arrest).
Blood potassium levels at below 6.5mmol/litre, poisoning is minimal, moderate up to 8mmol/litre and severe above 8mmol/litre. Absolute toxicity is governed by pH and sodium levels.
Hyperkalaemia symptoms may be transiently controlled with calcium gluconate, glucose or glucose and insulin, sodium bicarbonate or hypertonic sodium infusions, cationic exchange resins or haemo and peritoneal dialysis. ECG should be closely monitored.
Patients who are digitalized may experience acute digitalis intoxication during potassium removal.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Potassium citrate and citric acid renders the urine alkaline thereby providing relief of the symptoms of cystitis.

5.2. Pharmacokinetic properties

Alkalisation of the urine affects the growth of pathogens. The growth of *Esch.coli* is inhibited at a pH above 7.5. Alkalised urine is soothing to the epithelium of the bladder and urethra than the natural acid urine (symptoms of cystitis).

5.3. Preclinical safety data

The active ingredients of Effercitrate tablets are simple compounds with a well established medical use and recognised efficacy and an acceptable level of safety.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Saccharin Sodium
Lemon Flavour
Lime Flavour
Macrogol 6000
Copovidone
Magnesium Stearate

6.2. Incompatibilities

None known.

6.3. Shelf life

Three years.

6.4. Special precautions for storage

Do not store above 25°C. Replace cap securely to protect the tablets from moisture.

6.5. Nature and contents of container

Polypropylene tube with plastic cap incorporating a desiccant disc, containing 12 effervescent tablets.

6.6. Special precautions for disposal

Not applicable

7. MARKETING AUTHORISATION HOLDER

Cambridge Healthcare Supplies Limited
Unit 1 Chestnut Drive
Wymondham
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8. MARKETING AUTHORISATION NUMBER

PL 16794/0009

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

January 1980 / 31 March 2012

10. DATE OF (PARTIAL) REVISION OF THE TEXT

January 2017