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SCHEDULING STATUS:

Not Scheduled

PROPRIETARY NAME (and dosage form):

Uri-Alk (Effervescent Tablets)

COMPOSITION:

Each effervescent tablet contains:

Sodium Citrate.$2H_2O$	615 mg
Sodium Bicarbonate	1362 mg
Tartaric Acid	860 mg
Citric Acid Anhydrous	700 mg

Inactive ingredients: aspartame, lemon flavour, polyethylene glycol, quinolene yellow colourant, sodium carbonate anhydrous.

PHARMACOLOGICAL CLASSIFICATION:

A. 18.3 ion-exchange preparations

INDICATIONS:

Uri-Alk is a gastric antacid and urinary alkalising agent.

CONTRA-INDICATIONS:

Uri-Alk should not be administered to patients with severe renal disease, metabolic or respiratory alkalosis, hypocalcaemia or hypochlorhydria.

Uri-Alk should not be administered with urinary tract antiseptics which require an acid urine, such as methanamine mandelate and methanamine hippurate.

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WARNINGS AND SPECIAL PRECAUTIONS:

Uri-Alk should be used with care in patients suffering from renal insufficiency. Patients with renal disease should have periodic determinations of serum electrolytes to ensure that acid-base balance is maintained.

Alkalising agents do not eradicate bacteraemia although they may temporarily relieve lower urinary tract symptoms.

Concomitant use of Uri-Alk with an antacid by patients with compromised renal function may result in the absorption of dangerously high amounts of aluminium.

Patients suffering from congestive cardiac or congestive heart failure, oedema, aldosteronism or hypertension should not use Uri-Alk except under the advice and supervision of a doctor.

Caution should be exercised in patients with peptic ulceration.

To avoid the condition of metabolic alkalosis, symptoms may include shortness of breath, muscle weakness and mental disturbances such as restlessness, convulsions and coma. Muscle hyper tonicity, twitching and tetany may develop especially in hypocalcaemia patients. Uri-Alk should not be taken by patients who are following a sodium restricted diet. **Excessive doses may lead to sodium overloading and hyper-osmolality**.

DOSAGE AND DIRECTIONS FOR USE:

ADULTS:

One to two effervescent tablets in half a glass of cold water 2 - 3 times daily, taken on an empty stomach and followed with additional water. Drink after tablet has completely effervesced.

CHILDREN: (6 - 12 year)

One effervescent tablet in half a glass of cold water 2 to 3 times daily, taken on an empty stomach and followed with additional water. Drink after tablet has completely effervesced.

SIDE-EFFECTS:

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Side-effects of bicarbonate after oral administration are mainly gastro-intestinal. Stomach cramps, flatulence, belching and nausea may occur if Uri-Alk is taken before it has completely effervesced.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Over dosage may result in metabolic alkalosis. Symptomatic treatment should be instituted with complete withdrawal of the product and the appropriate correction of fluid and electrolyte balances.

IDENTIFICATION:

A round, light yellow effervescent tablet with flat sides, and rough surfaces.

After effervescence a light yellow, lemon-flavoured, clear solution results.

PRESENTATION:

Plastic or aluminium tubes containing 12 tablets.

STORAGE INSTRUCTIONS ~~DIRECTIONS~~:

Store in a cool, dry place at or below 25°C.

Protect from light.

Keep out of reach of children.

REGISTRATION NUMBER:

31/18.3/0414

NAME AND BUSINESS ADDRESS OF THE REGISTRATION HOLDER:

MEDCHEM PHARMACEUTICALS (PTY) LTD.,

5 GOEDE HOOP

18 HILLVIEW

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NEWLANDS

PRETORIA

SOUTH AFRICA

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