1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS S0

PROPRIETARY NAME AND DOSAGE FORM

KAOSTATEX (suspension)

COMPOSITION

Each 30 ml of KAOSTATEX suspension contains:

Light kaolin	6,0 g
Pectin	0,12 g
Sodium lactate	0,0864 g
Potassium chloride	0,0414 g
Sodium chloride	0,0789 g

Excipients:

Benzoic acid, essence of banana, icing sugar, maize starch, powdered acacia, powdered tragacanth, purified water, sucrose

Preservative:

Benzoic acid 0,2 % *m/v*

Contains sugar: Sucrose 1,631 g

CATEGORY AND CLASS

A 11.9.2 Antidiarrhoeals: Special combinations

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

KAOSTATEX has protective and absorbent properties and provides supplemental electrolytes which replace salt losses as a result of diarrhoea.

INDICATIONS

Treatment of simple diarrhoea.

CONTRAINDICATIONS

Hypersensitivity to any of the ingredients.

WARNINGS AND SPECIAL PRECAUTIONS

A consequence of diarrhoea may be fluid and electrolyte depletion, and rehydration therapy may be necessary, especially in infants and young children.

If diarrhoea persists for longer than 3 days, consult your doctor.

Sodium salts should be used cautiously in patients with heart failure, high blood pressure, swelling of hands and feet or with excessive fluid accumulation in the lungs, impaired renal function, pre-eclampsia, cirrhosis of the liver and in patients receiving corticosteroids.

Potassium chloride should be given with care to patients with renal or adrenal insufficiency, cardiac disease, acute dehydration, heat cramps, severe burns and to patients receiving potassium-sparing diuretics or potassium supplements.

Excipients

KAOSTATEX contains sucrose which may have an effect on the glycaemic control of patients

with diabetes mellitus.

Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucrase-isomaltase insufficiency should not take KAOSTATEX.

INTERACTIONS

KAOSTATEX may reduce the absorption of other medicines from the gastrointestinal tract, if administered concomitantly.

HUMAN REPRODUCTION

Not known.

DOSAGE AND DIRECTIONS FOR USE

Children 1 to 5 years:

1 medicine measure (5 ml) four hourly.

Children 6 to 12 years:

2 medicine measures (10 ml) four hourly.

Adults:

3 medicine measures (15 ml) to 6 medicine measures (30 ml) four hourly.

The suspension should be thoroughly shaken before the administration of each dose.

SIDE EFFECTS

Not known.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Symptoms

Sodium retention leads to accumulation of fluids in the brain, lungs, hand and feet. Symptoms of too much sodium in the blood may include nausea, vomiting, diarrhoea, abdominal cramps, sweating, restlessness, weakness, thirst, irritability, muscular twitching and ridigity, reduced salivation and secretion of tears, swollen tongue, flushing of the skin, fever, dizziness, headache, low blood pressure, increased heart rate, renal failure, delirium, convulsions and respiratory arrest.

Excessive administration of potassium chloride or concurrent administration with potassium supplements may result in numbness or tingling of the extremities, muscle weakness, paralysis, low blood pressure, irregular heart beats, heart block and cardiac arrest.

Treatment

Treatment is symptomatic and supportive.

IDENTIFICATION

Off-white, thick-opaque suspension with a slight banana odour.

PRESENTATION

150 ml is packed in a polyvinyl chloride bottle, with a white linear, low density polyethylene snap-on cap.

STORAGE INSTRUCTIONS

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

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

F/11.9.2/181

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead

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DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

Date of registration: 07 June 1976

Date of the most recent amendment to the professional information as approved by the Authority: 07 June 1976

Botswana: B9315750 S3

Namibia: NS1 90/11.9.2/001007

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