1.3.1.1 PROFESSIONAL INFORMATION

The under-mentioned information with regard to this medicine shall appear on the package insert. The information shall be presented in the format stipulated, provided that the Council may authorize any deviation from such information or such format (Refer to Regulation 9 of the Act).

1. Scheduling status
2. Proprietary name and dosage form
3. Composition
4. Category and Class
5. Pharmacological action (pharmacokinetics, pharmacodynamics and summary of clinical studies, where applicable)
6. Indications
7. Contraindications
8. Warnings and Special Precautions
9. Interactions
10. Human Reproduction
11. Dosage and directions for use
12. Side effects
13. Known symptoms of over dosage and particulars of its treatment
14. Identification
15. Presentation
16. Storage instructions
17. Registration number (or reference number)
18. Name and business address of the holder of the certificate of registration
19. Date of publication of the professional information

SCHEDULING STATUS: **S4**

PROPRIETARY NAME (and dosage form)**:** KEXELATE® POWDER

COMPOSITION:

Sodium polystyrene sulfonate, a cation-exchange resin prepared in the sodium phase with an in vitro exchange capacity of approximately 3,1 mEq. (in vivo approximately 1 mEq.) of potassium per gram. Sodium content is approximately 100 mg per gram of the drug.

CATEGORY AND CLASS:

A.18.3 Ion-exchange preparations

PHARMACOLOGICAL ACTION:

As the resin passes along the intestine or is retained in the colon after administration by enema, the sodium ions are partially released and are replaced by potassium ions. For the most part, this action occurs in the large intestine, which excretes potassium ions to a greater degree than does the small intestine.

INDICATIONS:

The resin is recommended for the treatment of persons with hyperkalaemia associated with oliguria or anuria due to acute tubular necrosis (lower nephron nephrosis, haemoglobinuric nephrosis, shock kidney, crush injury).

CONTRAINDICATIONS:

No contraindications have been established.

WARNINGS and SPECIAL PRECAUTIONS:

Serious potassium deficiency may occur if the effective dosage range is exceeded. It is imperative, therefore, to determine the daily serum potassium levels. The drug should be discontinued when the serum potassium level reaches 4-5 mEq. per litre (16-20 mg per 100 ml). It should be noted that the severity of intracellular potassium depletion cannot be correlated with the levels of serum potassium, as in some cases severe intracellular depletion may occur and serum levels may be at the low-normal

stage. Since sodium is released in the intestine during electrolyte exchange, particular caution is advisable in the use of the resin in patients with actual or impending cardiac failure, and in such instances the total fluid intake should be restricted. The resin should be administered with caution to patients with acute or chronic renal failure since the large amounts of sodium released may induce heart failure, oedema, and severe hypertension.

The possibility of a serum calcium deficit should be considered and managed as described herein. Since cation exchange resins are not selective, magnesium loss may occur in prolonged treatment. Patients receiving repeated doses should be monitored for acid-base electrolyte and mineral metabolism. If constipation occurs, patients should be treated with a mild laxative as needed to provide one to two watery stools daily; a measure which also reduces any tendency to faecal impaction. In patients with lower potassium blood levels, the action of digitalis, particularly its toxic effects, is likely to be exaggerated. Electrocardiograms are of value in the diagnosis of hyperpotassaemia and hypopotassaemia, hypocalcaemia, and digitalis intoxication.

INTERACTIONS

Interaction studies have not been performed

HUMAN REPRODUCTION

Safety in pregnancy and lactation has not been established

DOSAGE AND DIRECTIONS FOR USE:

The average adult dose of the resin is 15 g taken orally one to four times daily.

Each dose should be given as a suspension in a small quantity of water or, for greater palatability, in syrup. The amount of fluid usually ranges from 20-100 ml, depending on the dose, or may be simply determined by allowing 3-4 ml per gram of resin. Sorbitol may be administered in order to combat constipation.

The resin may be introduced into the stomach through a plastic tube and if desired, mixed with a diet consisting of 400 g of glucose and 100 ml of peanut or olive oil diluted to 1 litre with distilled water, using gum acacia to emulsify the oil.

The resin may also be given although with less effective results, in a daily enema consisting (for adults) of 30 g once or twice daily. Each dose is administered as a warm emulsion (at body temperature) in 150-200 ml of aqueous vehicle (such as plain water, 10% dextrose in water, or equal parts of water and 2% methyl cellulose suspension). The emulsion should be agitated gently during administration. The enema should be retained for four to ten hours if possible and followed by a cleansing enema. With the proper technique, resin enemas are very effective in lowering serum potassium levels; the following technique is advocated. After the initial cleansing enema, a soft large size (French 28) rubber tube is inserted into the rectum for a distance of about 20 centimeters, with the tip well into the sigmoid colon, and taped in place. The resin is then suspended in the appropriate amount of water or 10% dextrose in water at body temperature and introduced by gravity, while the particles are kept in suspension by stirring. The suspension is kept in the sigmoid colon for four hours. Then, the colon is irrigated with normal saline at body temperature in order to remove the resin. Two litres of saline may be necessary.

The duration of therapy required with these doses may be as short as three days (although longer periods of treatment have been necessary in some patients), and depends on the serum potassium level, which should be determined daily. The drug should be discontinued when this level reaches 4-5 mEq. per litre (16-20 mg per 100 ml). To prevent undue calcium loss, the serum calcium level should also be determined in persons receiving the resin for more than a few days. Any necessary replacement may be given orally or intravenously.

In persons vomiting persistently, a supplementary nutrient may be given, consisting of a slow intravenous infusion of 40% dextrose into the superior vena cava through a plastic tube introduced into an antecubital vein.

SIDE-EFFECTS:

KEXELATE ® may cause some degree of gastric irritation. Anorexia, nausea, and vomiting may occur especially if high doses are given. Occasionally diarrhoea develops. Large doses in elderly individuals may cause faecal impaction. These effects may be obviated through use of the resin in enemas as described under "Dosage and Directions for Use."

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

No known symptoms of overdosage.

IDENTIFICATION:

Light brown finely ground powder.

PRESENTATION:

Jars of 454 g.

STORAGE INSTRUCTIONS:

Store at or below 25 °C. Keep out of reach of children.

REGISTRATION NUMBER:

H1748 (Act 101/1965)

BW: S2 B9323465

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

Adcock Ingram Critical Care (Pty) Ltd

1 Sabax Road

Aeroton

Johannesburg, 2013

P.O. Box 6888, Johannesburg, 2000

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION:

Date of Registration: January 1975

Date amended: 14/10/2015 (compliant with regulation 9)

* Registered Trade Mark