PROFESSIONAL INFORMATION
OSTEOEZE® ALKALINE POWDER

SCHEDULING STATUS
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PROPRIETARY NAME AND DOSAGE FORM
OSTEOEZE® ALKALINE POWDER (powder)

COMPOSITION

Active Ingredients	Elemental quantity per 5 grams	% NRV#
Potassium (as citrate)	600 mg	*
Calcium (as lactate)	250 mg	19,23 %
Magnesium (as citrate)	125 mg	41,66 %
Magnesium (as carbonate)	50 mg	
Zinc (as zinc citrate)	3 mg	27,27 %
Vitamin D3	400 IU	66,66 %

#Nutrient Reference Values for adults and children older than 4 years.
*NRV not established
Excipients: Acacia gum, citric acid, flavour, and lactic acid powder.
OSTEOEZE® ALKALINE POWDER has good digestive tolerability.
OSTEOEZE® ALKALINE POWDER is sugar and lactose free.
OSTEOEZE® ALKALINE POWDER contains the artificial sweetener sucralose: 23 mg/ 5 gram.

CATEGORY AND CLASS
D34.12 Complementary medicines: Health supplements - Multiple substance Formulation.

PHARMACOLOGICAL ACTION
Pharmacodynamic properties
OSTEOEZE® ALKALINE POWDER is a multi-mineral blend containing predominantly citrates without fillers, lactose or sugar. It contains magnesium, zinc, potassium, calcium and vitamin D in a powder format, which helps maintain the body's acid/alkaline balance. Base organic anions such as citrate are converted to bicarbonate by the liver after ingestion and bicarbonate is the blood's form of base where it is used to buffer excess acids. Some of the ingested citrate will also be excreted in the urine where it helps prevent calcium stone formation. The formula is high in potassium, have the correct ratio of calcium to magnesium and is sodium free. It simulates the effect of eating more fruits and vegetables in the body by supplying the citrate form of the minerals.
Pharmacokinetic properties
The active ingredients in this formulation are well known. Pharmacokinetic studies have not been conducted with OSTEOEZE® ALKALINE POWDER.

INDICATIONS
OSTEOEZE® ALKALINE POWDER will assist the body in maintaining its acid-alkaline balance and regulating urinary pH.
The citric acid salts are used for:
- Alkalinisation of the urine – especially long term (e.g. management of uric acid and cysteine calculi of the urinary tract)
- Chronic metabolic acidosis
- Adjuvants to gout therapy

By alkalinizing the urine, the excretion of uric acid is facilitated that prevent the formation of uric acid crystals.
Magnesium contributes to energy metabolism, electrolyte balance, the nervous system, normal muscle function and a reduction in tiredness and fatigue.
Zinc contributes to connective tissue formation and normal immune function.
Potassium contributes to normal muscle function and the nervous system.
Calcium contributes to muscle function, bone maintenance and neurotransmission.
Vitamin D contributes in the development and maintenance of bones and teeth and helps in the absorption and use of calcium.

CONTRAINDICATIONS
Hypersensitivity to any of the ingredients of OSTEOEZE® ALKALINE POWDER (see **COMPOSITION**).
Not recommended during pregnancy or lactation.
Not recommended for patients with hypercalcaemia, hyperkalaemia or impaired kidney function.
Not recommended for patients with metabolic or respiratory alkalosis. Not recommended for patients on potassium restricted diets or taking medicines that increase potassium levels.

WARNINGS AND SPECIAL PRECAUTIONS
Do not use if known hypersensitivity or allergy exist to any of the ingredients. If in doubt, consult your medical practitioner. Do not use during antibiotic use. Calcium salts may cause constipation and flatulence. Magnesium salts may cause gastrointestinal irritation and watery diarrhoea. Potassium salts may cause diarrhoea, vomiting, belching, flatulence, and ulcerations. Oral potassium is contraindicated in individuals with gastrointestinal motility conditions.
Porphyria: safety has not been established.
Effects on the ability to drive and use machinery: There are insufficient information available on the effects of OSTEOEZE® ALKALINE POWDER on the ability to drive or operate machinery.

INTERACTIONS
Adverse effects have not become known with the simultaneous ingestion of OSTEOEZE® ALKALINE POWDER and food and drink.
Calcium supplements are known to interact with many other medicines, especially thyroid medicine, tetracycline antibiotics, bisphosphonates and fluoroquinolones. OSTEOEZE® ALKALINE POWDER should therefore be administered 2 hours before, or 3 to 4 hours after taking other medication.
Calcium enhances the effects of digitalis glycosides on the heart and therefore OSTEOEZE® ALKALINE POWDER is not recommended for patients receiving cardiac glycosides. Calcium should be administered cautiously in patients with renal impairments and diseases associated with hypercalcemia.
Magnesium supplements may interact with other medication and decrease the effectiveness of antibiotics, enhance side effects of misoprostol and increase drug activity on hypoglycemics. OSTEOEZE® ALKALINE POWDER should therefore be administered 2 hours before, or 3 to 4 hours after these medicines. Magnesium salts should be administered cautiously in individuals with reduced kidney function due to an increased risk of hypermagnesemia. Oral potassium is contraindicated in individuals with gastrointestinal motility conditions. Potassium salts must be given with caution to patients with renal or adrenocortical insufficiency, cardiac disease or other conditions that may predispose to hyperkalemia. OSTEOEZE® ALKALINE POWDER should be used with caution in combination with other medicines that increase serum potassium concentrations or that contain potassium, such as potassium-sparing diuretics, ACE inhibitors, cyclosporin, potassium salts of penicillin, beta-blockers and potassium-containing salt substitutes.

HUMAN REPRODUCTION
Pregnancy and lactation
Safety during pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE
Do not exceed the recommended daily dosage.
Adults and children 12 years and older:
Take 5 grams (one medicine measure) dissolved in 150 ml of water daily with or after meals. Stir well. If the mineral salts leave a residue on the glass or on the spoon, wash this down with more water. For best alkalinising effect, take just before bedtime.

SIDE EFFECTS
If you experience any side effects or sensitivity towards any of the ingredients, discontinue use.
If symptoms persist, or if any adverse reactions occur, consult a medical practitioner.
Side effects may include, but are not limited to;
Calcium salts:
Gastro-intestinal disorders:
Frequent: Constipation and flatulence.
Magnesium salts:
Gastrointestinal disorders:
Frequent: gastrointestinal irritation and watery diarrhoea.
Potassium salts:
Gastrointestinal disorders:
Frequent: nausea, vomiting, diarrhoea, abdominal pain and flatulence.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
Symptoms of Overdosage:
See **SIDE EFFECTS**.
Do not exceed the recommended daily dosage.
OSTEOEZE® ALKALINE POWDER contains potassium and excessive intake of potassium salts may lead to hyperkalaemia.
If an accidental overdose occurs, consult a medical practitioner.
Treatment is symptomatic and supportive.

IDENTIFICATION
White powder with a berry flavour

PRESENTATION
White HDPE plastic container containing 150 grams of powder with an aluminium foil seal and green HDPE plastic screw cap, and a silica sachet in each container. Each container is packed with a leaflet into a unit carton.

STORAGE INSTRUCTIONS
Do not use if seal is broken.
Store at or below 25 °C.
The product may be refrigerated, if needed.
Replace cap firmly after use.
Protect from light and moisture.
Keep in original packaging until required for use.
Do not use after the expiry date printed on the carton and container.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER
To be allocated

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
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DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION
To be allocated

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COMPLEMENTARY MEDICINE
Health Supplement
Health Supplements are intended only to complement health or supplement the diet.
This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

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