

PATIENT INFORMATION LEAFLET

OSTEOEZE® ALKALINE POWDER

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

Complementary Medicine: Health supplement.

Health Supplements are intended only to complement health or supplement the diet

SCHEDULING STATUS

S0

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

OSTEOEZE® ALKALINE POWDER, (Powder)

Read all of this leaflet carefully because it contains important information for you.

OSTEOEZE® ALKALINE POWDER is available without a doctor's prescription, as a supplement. Nevertheless, you still need to use **OSTEOEZE® ALKALINE POWDER** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **OSTEOEZE® ALKALINE POWDER** with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve or if you notice any side effect not listed in this leaflet.

1. WHAT OSTEOEZE® ALKALINE POWDER CONTAINS

The active substances are:

Each dose of 5 grams contains the following elemental quantities:

Potassium 600 mg, calcium 250 mg, magnesium 175 mg, zinc 3 mg and vitamin D3 400 IU.

The other ingredients are: acacia gum, citric acid, flavouring, and lactic powder.

OSTEOEZE® ALKALINE POWDER contains the artificial sweetener, sucralose. **OSTEOEZE® ALKALINE POWDER** contains no sugar or lactose.

2. WHAT OSTEOEZE® ALKALINE POWDER IS USED FOR

OSTEOEZE® ALKALINE POWDER will assist the body in maintaining its acid alkaline balance and regulating urinary pH. By alkalanizing the urine, the excretion of uric acid is facilitated as well as preventing the formation of uric acid crystals.

For a diagnosis, consult a medical practitioner.

3. BEFORE YOU TAKE OSTEOEZE® ALKALINE POWDER

Do not take OSTEOEZE® ALKALINE POWDER

- If you are hypersensitive (allergic) to any of the ingredients of **OSTEOEZE® ALKALINE POWDER**.
- If you are pregnant or are breastfeeding your baby (see 'Pregnancy and breastfeeding') (see 'HOW TO TAKE OSTEOEZE® ALKALINE POWDER')
- If you are suffering from kidney failure.
- If you are suffering from kidney stones or have calcium deposits in your kidneys.
- If you have metabolic or respiratory alkalosis (excessive alkalinity).

Ask your doctor if you are not sure about any of the above.

Take special care with OSTEOEZE® ALKALINE POWDER and please consult your doctor or pharmacist prior to use if you:

- Have had kidney stones.
- Are taking any medicine containing calcium or potassium to avoid overdose.
- Do not take **OSTEOEZE® ALKALINE POWDER** if you are younger than 12 years, as it is not recommended below this age.
- Have kidney or adrenocortical (the cortex of the adrenal glands found above the kidneys) insufficiency, have conditions that may predispose to hyperkalaemia (high levels of potassium).
- Have been told by your doctor that you have an intolerance to any of the ingredients. (see **WHAT OSTEOEZE® ALKALINE POWDER CONTAINS**).

Taking OSTEOEZE® ALKALINE POWDER with food and drink

There are no known side effects to taking **OSTEOEZE® ALKALINE POWDER** with food and drink. Absorption is not affected by food or drink.

Pregnancy and Breastfeeding

Safety during pregnancy and breastfeeding has not been established.

Driving and using machinery

There is insufficient information on the effects of **OSTEOEZE® ALKALINE POWDER** on the ability to drive and use machinery.

Important information about some of the ingredients of OSTEOEZE® ALKALINE POWDER:

OSTEOEZE® ALKALINE POWDER contains the artificial sweetener, sucralose. **OSTEOEZE® ALKALINE POWDER** contains no sugar or lactose.

Taking other medicines with OSTEOEZE® ALKALINE POWDER

Interactions can be minimized by taking **OSTEOEZE® ALKALINE POWDER** and any other medication two hours before hand or two to three hours afterwards. Always tell your healthcare professional if you are taking any other medicine, including complementary or traditional medicines and other medicines obtained without a prescription. Do not use **OSTEOEZE® ALKALINE POWDER** in combination with medicines such as:

- Cardiac glycosides (medicine to treat heart problems), as they might cause undesired side effects.
- Antibiotics, bisphosphonates (medicine to treat bone conditions), thyroid medications, misoprostol (to prevent stomach ulcers when taking NSAIDS) and hypoglycemics.
- Beta-blockers (medicine to treat blood pressure) as they are known to increase potassium levels.
- Medicines that increases serum potassium concentrations or that contains potassium, such as potassium sparing diuretics, ACE inhibitors, cyclosporine, potassium salts of penicillin and potassium-containing salt substitutes.

4. HOW TO TAKE OSTEOEZE® ALKALINE POWDER

Do not share your medicines with any other person. Always take **OSTEOEZE® ALKALINE POWDER** exactly as indicated or as your pharmacist has instructed you. You should check with your pharmacist if you are unsure.

Adults, elderly and children over 12 years of age:

Measure 5 grams (one medicine measure) into a glass. Add 150 ml of water. Stir well and drink. Take with or after meals. For best alkalizing effect, take at night at bedtime.

Children under 12:

OSTEOEZE® ALKALINE POWDER should not be given to children under 12 years old.

If you take more OSTEOEZE® ALKALINE POWDER than you should:

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take / missed a dose of OSTEOEZE® ALKALINE POWDER

Take your missed dose when you remember. Do not take a double dose to make up for forgotten individual doses.

Effects when treatment with OSTEOEZE® ALKALINE POWDER is stopped

When you are taking the dose as indicated, it is unlikely that there should be withdrawal effects. However, always tell your pharmacist before stopping the use of **OSTEOEZE® ALKALINE POWDER**.

5. POSSIBLE SIDE EFFECTS

OSTEOEZE® ALKALINE POWDER may have side effects such as:

- May cause constipation, nausea, vomiting, diarrhea, abdominal pain and flatulence.
- **OSTEOEZE® ALKALINE POWDER** contains potassium and excessive intake of potassium salts may lead to the accumulation of potassium and high levels of potassium (hyperkalaemia). Closely monitor potassium levels.

Should your general health worsen or if you experience any undesired effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Not all side effects are included in this leaflet. If you notice any other side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF OSTEOEZE® ALKALINE POWDER

Store at or below 25 °C.

Protect from direct sunlight and moisture.

Keep the container tightly closed. Keep in the carton until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label and carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

7. PRESENTATION OF OSTEOEZE® ALKALINE POWDER

White HDPE plastic container containing 120 grams of powder with aluminium foil seal and green HDPE plastic screw cap, and a silica sachet and measuring spoon in each container. Each container is packed into a unit carton.

8. IDENTIFICATION OF OSTEOEZE® ALKALINE POWDER

White powder with a berry flavour.

9. REGISTRATION NUMBER

To be allocated

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Nativa (Pty) Ltd

260 Cradock Avenue, Lyttelton, Centurion, 0157, Gauteng, South Africa

Tel: +27 (0) 12 664 7110

Customer care line: **0860 628 482**

Email: health@nativa.co.za

Website: www.nativa.co.za

11. DATE OF PUBLICATION

To be allocated

12. DATE OF REGISTRATION

To be allocated

13. Category D

Classification: D 34.12 Multiple substance formulation. Health Supplement.

The **OSTEOEZE® ALKALINE POWDER** professional information may be obtained from the Nativa website (www.nativa.co.za).

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