The Real Thing Zeolite Powder

Complementary Medicine. Health Supplement.

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

SCHEDULING STATUS: S0

1 NAME OF THE MEDICINE
THE REAL THING ZEOLITE POWDER contains 100 % *m/m* zeolite (clinoptilolite).

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 4,5 g of powder contains 100 % *m/m* pure zeolite powder.
There is no free silica. The powder is sugar free.

3 PHARMACEUTICAL FORM
THE REAL THING ZEOLITE POWDER is a pale beige/grey coloured powder with a soft, fluffy feel to it. It has a bland taste when mixed with water.

4 CLINICAL PARTICULARS
4.1 Therapeutic indications
THE REAL THING ZEOLITE POWDER is a health supplement that –
- is a source of minerals, which are beneficial for overall good health.

4.2 Posology and method of administration
Orally: Adults 18 years and older: After food, take 1 tablespoon (approximately 4,5 g) daily for at least 30 days. Mix with water or a liquid of your choice. Mix well and drink quickly. If dryness of mouth is experienced, drink plenty of water.

For acute health problems, consult your health care practitioner.
Face mask: Mix 1 to 2 tablespoons with a little water to make a paste. Before the paste dries, apply evenly over face (and neck and chest if desired). After 10 minutes, rinse off with water and mild soap. Use once every two weeks. If skin feels dry after application, follow up with a moisturiser. If irritation of the skin occurs, discontinue use and consult your health care practitioner.

Paediatric population
THE REAL THING ZEOLITE POWDER is not suitable for use in children.

4.3 Contraindications
Hypersensitivity to the ingredient.

4.4 Special warnings and precautions for use
None known.

4.5 Interaction with other medicines and other forms of interaction
None known.

4.6 Fertility, pregnancy and lactation
Safety during pregnancy and lactation has not been established. Use only on the recommendation and under the supervision of a health care practitioner. No fertility data is available.

4.7 Effects on ability to drive and use machines
THE REAL THING ZEOLITE POWDER has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects
a. Summary of the safety profile
Gastrointestinal disorders and skin irritation are the reported undesirable effects.

b. List of adverse reactions
Gastrointestinal disorders
Zeolite ingested orally could cause diarrhoea although it can be clinically used to combat diarrhoea, or could cause flatulence. Zeolite is a dry, highly adsorbent powder and could have a dehydrating effect or cause irritation when taken orally.
Respiratory disorders
Zeolite ingested orally could cause dry cough.
Skin and subcutaneous tissue disorders
Topical application could result in skin dryness and irritation.
Frequencies of all adverse effects are not known.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care practitioners are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.
Alternatively, suspected adverse reactions may be reported directly to the Holder of the Certificate of Registration, The Real Thing Food Supplements (Pty) Ltd at telephone 021-701 0244 or e-mail adr@therealthing.co.za

4.9 Overdose
With an overdose, side effects can be precipitated and/or be of increased severity.
Orally the dehydrating effect could cause thirst, irritation or other symptoms such as dry cough and gagging. Wash out mouth with water and drink plenty of water. Seek medical attention if severe symptoms develop.
Topically skin dryness, irritation and chapping may occur. Rinse the skin with water and use skin moisturizer to soothe the skin.
Inhalation could result in respiratory irritation, dry cough and shortness of breath. Remove the person to fresh air, and rinse the mouth and nasal passages with water.
Eye contact could result in irritation, itchiness and corneal scratching. Remove contact lenses if wearing these, and immediately flush the eyes with water for 15 minutes.
In all of the above cases if irritation persists or worsens, seek medical attention.
Treatment of overdosage is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
THE REAL THING ZEOLITE POWDER belongs to category D Complementary Medicines, Health Supplements, class 34.7, Minerals.

THE REAL THING ZEOLITE POWDER is comprised of clinoptilolite, the most abundant natural source of zeolite, which is included as a health supplement based on –

- its ability to donate minerals, which are beneficial to the nutritional status of the human body.

Zeolites are aluminosilicate minerals with rigid anionic frameworks containing well-defined negatively charged channels and cavities. These cavities are occupied by positively charged alkali, and alkali earth monovalent (Na^+, K^+), and divalent (Ca^{2+}, Mg^{2+}) ions, OH-groups or H_2O molecules (water).
Zeolite's mineral structure is based on AlO_4 and SiO_4 tetrahedra. Zeolite has a molecular formula of $(Mg\ Ca\ Na_2\ K_2)_{2,5.}\ (AlO_2)_7\ (SiO_2)_{30}.\ 21\ H_2O$.

5.2 Pharmacokinetic properties
Orally, zeolite is not absorbed or metabolised by the body.
Lead adsorption by zeolite takes place at pH 3 to 11. Leaching of lead from preloaded clinoptilolite occurs mainly at pH below 1, which is not relevant to conditions in the human body.
Clinoptilolite donates its alkali and alkali earth monovalent and divalent metals.

Paediatric population
No information is available.

6 PHARMACEUTICAL PARTICULARS
6.1 List of excipients
There are no inactive ingredients.

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
THE REAL THING ZEOLITE POWDER has a shelf life of 2 years when stored in a cool, dry place at or below 25 °C.

6.4 Special precautions for storage
Keep container tightly closed.

6.5 Nature and contents of container
THE REAL THING ZEOLITE POWDER is packed in a labelled hard cardboard container fitted with a metal base and tamper-evident AluPeel top, covered with a clear plastic snap-on lid. The container is lined with a sealed clear plastic bag. The pack contains 300 g of powder.

6.6 Special precautions for disposal
No special requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION
THE REAL THING FOOD SUPPLEMENTS (PTY) LTD
9 Westlake Drive
Westlake 7945, Cape Town
Telephone: 021-701 0244
E-mail: info@therealthing.co.za

8 REGISTRATION NUMBER
(To be allocated)

9 DATE OF FIRST AUTHORISATION

(To be allocated)

10 DATE OF REVISION OF THE TEXT

This is the first edition.

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