

PROPOSED PROFESSIONAL INFORMATION

COMPLEMENTARY MEDICINE – HEALTH SUPPLEMENT

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

SCHEDULING STATUS S0

PROPRIETARY NAME AND DOSAGE FORM

PCOSITOL powder

COMPOSITION

Each sachet contains:

Myo-inositol	4 000 mg
D-chiro-inositol	100 mg
Co-enzyme Q ₁₀	100 mg
Magnesium glycinate	350 mg
Folic acid (L-5-methyltetrahydrofolate)	500 µg
Vitamin B ₁₂ (Methylcobalamin)	25 µg
Chromium polynicotinate	30 µg
Zinc oxide	25 mg
Calcium (Calcium carbonate)	500 mg
Vitamin D ₃	1 000 IU
Vitamin K ₂	45 µg

Excipients: Berry flavour, citric acid, maltodextrin, sucralose
Contains sweetener (sucralose 50 mg/sachet)

CATEGORY AND CLASS

D34.12 Multiple substance formulation

PHARMACOLOGICAL ACTION

Inositol

Inositol is an essential component of cell membrane phospholipids. Inositol has a variety of stereoisomers, including myo-inositol and D-chiro-inositol.

Myo-inositol is the most abundant form in the central nervous system (CNS).

D-chiro-inositol isomer induces ovulation in women with polycystic ovary syndrome by improving insulin sensitivity.

Myo-inositol and D-chiro-inositol

The combination of myo-inositol and D-chiro-inositol is better than taking each alone. It is postulated that D-chiro-inositol may be better at improving metabolic profiles in patients with polycystic ovary syndrome, while myo-inositol may be better at improving ovulatory function.

Co-enzyme Q₁₀

Co-enzyme Q₁₀ is an antioxidant for the maintenance of good health.

Magnesium glycinate

Helps the body to metabolise carbohydrates, proteins and fats. It helps with the development and maintenance of bone and teeth and maintain proper muscle function. It also helps with the forming of tissue.

Folic acid (L-5-methyltetrahydrofolate)

Folic acid helps the body to metabolise protein and with forming of red blood cells.

Myo-inositol and folic acid

Taking myo-inositol plus folic acid improves menstrual cycle length, reduces insulin resistance (HOMA-IR) and hyperinsulinemia, improves insulin sensitivity, and decreases weight.

Vitamin B₁₂ (Methylcobalamin)

Vitamin B₁₂ helps to metabolise carbohydrates, fats and proteins and is a factor in the maintenance of good health. It also contributes to normal red blood cell formation.

Chromium polynicotinate

Chromium provides support for healthy glucose metabolism and helps to metabolise carbohydrates and fats.

Zinc oxide

Zinc helps in connective tissue formation and maintaining healthy skin and immune function. It also helps to metabolise carbohydrates, proteins and fats.

Calcium (Calcium carbonate)

Calcium is a mineral that is necessary to build bones and teeth and keeping them healthy. Calcium intake, when combined with sufficient vitamin D, a healthy diet, and regular exercise, may reduce the risk of developing osteoporosis.

Vitamin D₃

Vitamin D₃ helps with the development and maintenance of bones and teeth. It also assists with the absorption of calcium and phosphorus.

Vitamin K₂

Vitamin K₂ contributes to the maintenance of normal bones.

INDICATIONS

Nutritional supplement to support female patients suffering from polycystic ovary syndrome.

CONTRAINDICATIONS

Hypersensitivity to any of the ingredients.

WARNINGS AND SPECIAL PRECAUTIONS

Myo-inositol can lower blood glucose levels and may cause hypoglycaemia. Dose adjustments to diabetes medicine may be necessary (see **INTERACTIONS**).

Co-enzyme Q₁₀ can lower blood pressure. Dose adjustments to high blood pressure medicine may be necessary (see **INTERACTIONS**).

Effects on ability to drive and use machines

PCOSITOL should not have any effect on your ability to drive or to use machines.

INTERACTIONS

Concomitant use of myo-inositol and anti-diabetic medicines or other herbal products with hypoglycaemic potential might increase the risk of hypoglycaemia (see **WARNINGS AND SPECIAL PRECAUTIONS**).

The myo-inositol levels can be lowered by carbamazepine, lithium and valproate.

Co-enzyme Q₁₀ can lower blood pressure. Dose adjustments to high blood pressure medicine may be necessary (see **WARNINGS AND SPECIAL PRECAUTIONS**).

HUMAN REPRODUCTION

Safety in pregnancy and lactation has not been established.

DOSEAGE AND DIRECTIONS FOR USE

Drink the content of one sachet daily. Mix one sachet in a glass of water, stir and drink immediately.

SIDE EFFECTS

Myo-inositol in **PCOSITOL** is associated with very few and only mild side effects. Nausea, tiredness, headache and dizziness may occur.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

An overdose of **PCOSITOL** should be treated symptomatically and supportively.

IDENTIFICATION

Free flowing, pink coloured, berry flavoured powder.

PRESENTATION

Carton box containing 30 sachets and leaflet. Each sachet contains 8 g **PCOSITOL** powder.

STORAGE INSTRUCTIONS

Store at or below 25 °C in a dry place.
KEEP OUT OF REACH OF CHILDREN

REGISTRATION NUMBER

To be allocated

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

Delfran Pharmaceuticals (Pty) Ltd
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DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION

Date of registration: To be allocated

Date of most recent approved amendment: Not applicable