PMX™ Film-coated Tablets and Soft-Gel Capsules

PROFESSIONAL INFORMATION

Complementary Medicine – Health Supplement

SCHEDULING STATUS

To be assigned

1. NAME OF THE MEDICINE

PMX™ Film-coated Tablets and Soft-Gel Capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

PMX™ is comprised of 2 Components:

Component 1

Each Pink Tablet contains:

Vitamin B6 derived from Pyridoxal-5-Phosphate Monohydrate 54 mg	**50**	**mg**
Vitamin B12 derived from Methylcobalamin 50 µg	**50**	**µg**
Vitamin D3 derived from Cholecalciferol 10 mg	**1 000**	**IU**
Biotin	**100**	**µg**
Folate derived from (6S)-5-Methyltetrahydrofolate 226 µg	**200**	**µg**
Inositol derived from Myo-Inositol 100 mg D-Chiro-Inositol 2,5 mg	**102,5**	**mg**
Iron derived from Ferrous Bisglycinate 25 mg	**5**	**mg**
Magnesium derived from Magnesium Oxide 332 mg	**200**	**mg**
Zinc derived from Zinc Oxide 25 mg	**20**	**mg**

All minerals are expressed in their elemental and non-elemental forms.

Sucrose, Lactose, Gluten and Tartrazine Free.

For full list of excipients, see section 6.1.

Component 2

Each Soft-Gel Capsule contains:

Evening Primrose Oil *(Oenothera biennis)* 65 – 85% Linoleic Acid 9% Gamma-Linoleic Acid [Seed]	**500**	**mg**
Vitamin E derived from d-α-Tocopherol Acetate 200 mg	**200**	**IU**

Soft Gelatine Capsule shell of Fish Origin.

Sucrose, Lactose, Gluten and Tartrazine Free.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated Tablets and Soft-Gel Capsules.

Component 1:
Pink Oval shaped Film-coated Tablet.

Component 2:
Clear shell Oval shaped Soft-Gel Capsule filled with a Yellow coloured oily liquid.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

PMX™ is a health supplement intended to support the symptoms associated with Premenstrual Syndrome in young females.

4.2 Posology and method of administration

For oral use.

Take one Pink Film-coated Tablet in the Morning with Breakfast and one Soft-Gel Capsule in the Evening with Dinner.

Take 2 hours before or after taking other medications or natural health products.

4.3 Contraindications

Do not use if you have a hypersensitivity to any of the ingredients, including the excipients listed in section 6.1.

PMX™ should not be used by persons suffering from:
- conditions associated with hypercalcaemia and hypercalciuria, and in renal impairment (chronic);
- renal osteodystrophy with hyperphosphataemia (risk of metastatic calcification).
- a Fish Allergy.

Consult a qualified healthcare professional prior to use if you have renal/kidney disease, or a seizure disorder.

4.4 Special warnings and precautions for use

High dose Zinc supplementation may cause a Copper or Iron deficiency.

Vitamin D may increase the risk of hypercalcaemia.

The Soft-Gel Capsule may contain traces of soybeans, fish and products thereof.

Not suitable for children below the age of 12 years (due to the Folate and Evening Primrose Oil content) unless under the direct supervision of a qualified healthcare professional.

4.5 Interactions with other medicines

Alcohol: excessive intake of alcohol may increase renal excretion of Magnesium and increases the turnover of Pyridoxine.

Calcitonin: effect of calcitonin may be antagonised by Vitamin D.

Digoxin: caution because hypercalcaemia caused by Vitamin D may potentiate effects of digoxin, resulting in cardiac arrhythmias.

Phenothiazines: risk of increased epileptic fits.

4-Quinolones: Magnesium may reduce absorption of 4-quinolones if not given 2 hours apart.

Tetracyclines: Magnesium and Zinc may reduce absorption of tetracyclines if not taken 2 hours apart.

Thiazide diuretics: Vitamin D may increase risk of hypercalcaemia and may increase excretion of Magnesium.

Zinc: may cause a reduced absorption of ciprofloxacin and penicillamine.

Vitamin D analogues (alfacalcidol, calcitriol, dihydrotachysterol): increased risk of toxicity with Vitamin D supplements.

4.6 Fertility, Pregnancy and Breastfeeding

Always check with your doctor or pharmacist before taking any medicines if you are pregnant, planning to have a baby or breastfeeding.

The safety of the Evening Primrose Oil as contained in PMX™ has not been established in pregnancy and breastfeeding.

4.7 Effects on ability to drive and use of machines

None.

4.8 Undesirable effects

Organ System	Less Frequent
Gastrointestinal discomfort	Nausea, diarrhoea, constipation, indigestion, bloating and flatulence

Reporting of suspected adverse reactions:
If you experience any adverse reactions not mentioned in this leaflet, report it to AnaStellar Brands (Pty) Ltd via pharmacist@anastellar.co.za, (011) 792 4601 or https://anastellar.co.za

4.9 Overdose

Treatment of overdose should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Biotin: Biotin functions as an integral part of the enzymes that transport carboxyl units and fix carbon dioxide. Biotin enzymes are important in carbohydrate and lipid metabolism, and are involved in gluconeogenesis, fatty acid synthesis, propionate metabolism, and the catabolism of amino acids.

Evening Primrose Oil: Evening Primrose Oil contains gamma-linolenic acid (GLA) and linoleic acid. GLA is a precursor of dihomogamma-linolenic acid, series 1 prostaglandins (PGE1) and arachidonic acid. PGE1 inhibits platelet aggregation and is also a vasodilator with less inflammatory effects.

Folate: Folates are involved in a number of single carbon transfer reactions, especially in the synthesis of purines and pyrimidines (and hence the synthesis of deoxyribonucleic acid (DNA), glycine and methionine). They are also involved in some amino acid conversions and the formation and utilisation of formate. Deficiency leads to impaired cell division (effects most noticeable in rapidly regenerating tissues).

Inositol: Plays an important role as the structural basis for a number of secondary messengers in eukaryotic cells, including inositol phosphates, phosphatidylinositol (PI) and phosphatidylinositol phosphate (PIP) lipids.

Iron: Iron is a component of haemoglobin, myoglobin and many enzymes that are involved in a variety of metabolic functions, including transport and storage of oxygen, the electron transport chain, DNA synthesis, and catecholamine metabolism.

Magnesium: Magnesium is an essential cofactor for enzymes requiring adenosine triphosphate (ATP) (these are involved in glycolysis, fatty acid oxidation, and amino acid metabolism). It is also required for the synthesis of ribonucleic acid (RNA) and replication of deoxyribonucleic acid (DNA); neuromuscular transmission; and calcium metabolism.

Vitamin B6: Vitamin B6 is converted in erythrocytes to pyridoxal phosphate and, to a lesser extent, pyridoxamine phosphate. It acts as a cofactor for enzymes that are involved in more than 100 reactions affecting protein, lipid, and carbohydrate metabolism. Pyridoxal phosphate is also present in the synthesis of several neurotransmitters; the metabolism of several vitamins (e.g. the conversion of tryptophan to Niacin); and haemoglobin, and sphingosine formation.

Vitamin B12: Vitamin B12 is active in the recycling of Folate coenzymes and the degradation of valine. It is also required for nerve myelination, cell replication, haematopoiesis, and nucleoprotein synthesis.

Vitamin D: Vitamin D is essential for promoting the absorption and utilisation of Calcium and Phosphorus and normal calcification of the skeleton. Along with parathyroid hormone (PTH) and calcitonin, it regulates serum Calcium concentration by altering serum Calcium and Phosphate blood levels as needed, and mobilising Calcium from bone. It maintains neuromuscular function and various other cellular processes, including the immune system and insulin production.

Vitamin E: Vitamin E is an antioxidant, protecting polyunsaturated fatty acids in membranes and other critical cellular structures from free radicals and products of oxidation. It works in conjunction with dietary Selenium (a cofactor for glutathione peroxidase), and also with Vitamin C and other enzymes, including superoxide dismutase and catalase.

Zinc: Zinc is an essential component of over 200 enzymes. It plays an important role in the metabolism of proteins, carbohydrates, lipids and nucleic acids. It is a cofactor in a range of biochemical processes, including the synthesis of DNA, RNA, and protein.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Component 1:

Tablet Core:
Calcium Phosphate Dibasic
Magnesium Stearate
Povidone
Silicon Dioxide
Solvent 45
Sodium Starch Glycolate

Tablet Coating:
Castor Oil
Flexicoat Pink
Shellac

Component 2:

Gelatin (Fish origin)
Glycerol

6.2 Incompatibilities

None.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store at or below 25 °C.
Protect from light and moisture.
Keep the blister strips in the outer carton until required for use.
KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

Component 1:
10 x Pink Film-coated Tablets contained in each of 3 x PVC/PVDC/Aluminium blister strips.

Component 2:
10 x Soft-Gel Capsules contained in each of 3 x PVC/PVDC/Aluminium blister strips.

Packed product:
6 x Blister strips enclosed within a cardboard carton.
Pack size of 30 x Film-coated Tablets of component 1 with 30 x Soft-Gel Capsules of component 2.

6.6 Special precautions for disposal

No special requirements.

7. Holder of Certificate of Registration

AnaStellar Brands (Pty) Ltd.
PO Box 639
Fontainebleau
2032
South Africa
+27 (0)11 792 4601

8. Registration number

To be assigned

9. Date of first authorisation

Not applicable

10. Date of revision of the text

November 2023

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