

(Myo-Inositol 550 mg + D-Chiro-Inositol 13.8 mg + Metformin Hydrochloride 500 mg + L-Methylfolate Calcium 0.5 mg + Mecobalamin 750 mcg Tablet)

Composition:

Each film coated tablet contains:

Myo-Inositol IP	550 mg
D-Chiro-Inositol	13.8 mg
Metformin Hydrochloride IP	500 mg
L-Methylfolate Calcium	0.5 mg
Mecobalamin IP	750 mcg
Excipients	q.s

Clinical Pharmacology:

Myo-Inositol:

A deficiency of Inositols has been postulated as a key factor in the pathogenesis of PCOS. An increased excretion of inositol in urine has also been observed in patients of PCOS thus leading to its deficiency. Based on these findings, inositols were used for the management of PCOS. Inositols (6 carbon polyols) are second messengers which are responsible for glucose transport intracellularly. It also increases the translocation of GLUT 4 to the cell membrane. At ovarian level, it has been observed that myoinositol based second messenger is involved in bothglucose uptakeand FSHsignalling. Variousstudies havefound a success rangingfrom22 to 88% in the management of PCOS. Though the side effects are minimal, the cost of treatment with 2-4g/day for 3-6 months duration is one of the major constraints.

D-Chiro-inositol:

D-chiro-inositol is part of a glycosyl phosphatidylinositol complex embedded in cell membranes that directs the activity of insulin inside the cell. Myo-inositol and D-chiro-inositol are intracellularly incorporated into inositol phosphoglycans (IPGs), which are second messengers of insulin, and some actions of insulin are mediated by these IPG mediators.

In the ovary, D-chiro-inositol is involved in insulin-mediated androgen synthesis, and exists in balance with myo-inositol. Imbalance of ovarian myo-inositol and D-chiro-inositol concentrations can adversely affect Follicle-Stimulating Hormone (FSH) signaling. Severalstudies have emphasized the pivotal role of inositols in improving oocyte quality. A number of studies have suggested that insulin pathway issues could relate to the IPG second messenger system. D-chiro-inositol supplementation has been shown to replenish stores of the mediator and improve insulin sensitivity in women.

Metformin:

Metformin, a time-tested drug for PCOS and has been used since long, in a dose of 500 mgthree times a day with a success rate of 20 to 96%. 5-11 it acts by suppressing hepatic gluconeogenesis. It also increases insulin sensitivity, enhances peripheral glucose uptake, and decreases insulin induced suppression of peripheral fatty acid oxidation. As both myoinositol and metformin have different mechanisms of action in improving insulin resistance and controlling hyperinsulinemia, it has been postulated that both the drugs in combination may have additive effect in management of hyperinsulinemia in PCOS with the reduction in the doses of individual drug to achieve similar efficacy.

L-Methylfolate Calcium: The term folate is typically used as a generic name for the group of chemically related compounds based on the folic acid structure. Folate, or vitamin B9, isthought of as one of the 13 essential vitamins. It cannot be synthesized de novo by the body, and must be obtained either from diet or supplementation. Neither folate nor folic acid is metabolically active. Both must be reduced to participate in cellular metabolism. L-5- Methyltetrahydrofolate (L-methylfolate) is the predominant micronutrient form of folate that circulates in plasma and that is involved in biologic processes. To become metabolically active, folic acid must first be converted to dihydrofolate (DHF) and then tetrahydrofolate (THF) through enzymatic reduction, a process catalyzed by the enzyme DHF reductase (DHFR). Thereafter, THF can be converted to the biologically active L-methylfolate by the enzyme methylenetetrahydrofolate reductase (MTHFR). This key conversion is necessary to provide L- methylfolate for the one-carbon transfer reactions (methyl donations) needed for purine/pyrimidine synthesis during DNA and RNA assembly, for DNA methylation, and to regulate homocysteine metabolism.

Methylcobalamin:

Methylcobalamine works by functioning in the production of a compound called myelin, which covers and protect nerve fibers. Methylcobalamin rejuvenates the damaged neuron. Without enough Methylcobalamin, myelin sheath does not form properly due to which nerve fibers suffers and people experience irreversible nerve damage. Methylcobalamin is used as acofactor in Methionine transferase enzyme, an enzyme which converts amino acid homocysteine to Methionine via folate cycle.

Indication:

- PCOS/PCOD.
- > Diabetic women for improving constipation rates.
- > Treating metabolic comorbidities and treat ovarian dysfunction.

Contraindications:

- Homet-Myo tablets contraindicated in renalimpairment, cardiovascular collapse (shock), acute myocardial infarction, and septicemia.
- Hypersensitivity to Metformin.
- Acute or chronic metabolic acidosis, including diabetic ketoacidosis. Diabetic ketoacidosis should be treated with insulin.

Overdose: Lactic acidosis has been reported due to over dose.

Route of administration: Oral.

Dosage: As directed by the Physician.

Storage: Store protected from light & moisture ,at atemperaturenotexceeding25°C. Keep out of reach children.

SCHEDULE G PRESCRIPTION DRUG-CAUTION: It is dangerous to take this preparation except under medical supervision.

Presentation: Homet-Myo tablet available as 10x10 Tablets.

Marketed by:



EPIONE PHARMACEUTICALS PVT.LTD.

804, Suyog Center, Gultekdi, Pune-411037 (MH), India.