

## **Dimple™**

### **CONTRACEPTIVE INJECTION**

Medroxyprogesterone Acetate Injection IP

150mg/mL-1mL Vial

For intramuscular use only

**Therapeutic Indications:** For the prevention of pregnancy.

**Dosage and Administration:** Dimple™ Contraceptive Injection 1 ml vial, the recommended dose is 150 mg every 3 months and is administered by deep IM injection in Gluteal or Deltoid muscle.

**Precaution:** Caution should be exercised in, taking history and physical examination with special reference to breast and pelvic organs, as well as Papanicolaou smear; in conditions influenced by fluid retention such as epilepsy, migraine, asthma, and cardiac or renal dysfunction, and there can be weight gain, delayed return of fertility, CNS disorders and convulsions, decrease in glucose tolerance, and jaundice. **Warnings:** Effect on bone mineral density, altered menstrual bleeding, slight or no increased overall risk of breast cancer and no overall increased risk of ovarian, liver, or cervical cancer and a prolonged, protective effect of reducing the risk of endometrial cancer, thromboembolic disorders, ocular disorders, unexpected pregnancy and ectopic pregnancy. **Contraindications:** Known or suspected pregnancy or as a diagnostic test for pregnancy, Undiagnosed vaginal bleeding, known or suspected malignancy of breast, active thrombophlebitis, or current or past history of thromboembolic disorders, or cerebral vascular disease, significant liver disease, known hypersensitivity to Medroxyprogesterone Acetate or any of its other ingredients, known case of complicated diabetes or diabetes more than 20 years.

**Adverse effects:** Menstrual irregularities (bleeding and /or amenorrhea), weight changes, headache, nervousness, abdominal pain/bloating and discomfort, dizziness, mood changes, decreased libido, loss of bone density.

**Dose Forms and Strengths:** Each 1 ml of vial contains 150mg of Medroxyprogesterone Acetate.

**Storage:** At temperature between 15°C to 30°C and protected from light. Do not freeze.

**Manufactured in India by:** Mylan Laboratories Ltd, Plot No:- 20 & 21, Pharmez, Sarkhej-Bavla, National Highway No.8- A, Near Village Matoda, Tal.-Sanand, Dist.-Ahmedabad – 382 213. Gujarat, India.

**Marketed by:** Mylan Pharmaceuticals Private Limited, Plot No. 1-A/2, MIDC Industrial Estate, Taloja, Panvel, District: Raigad, Maharashtra - 410 208, India

Abbreviated Prescribing Information Version 12/2016.

Please refer to the full Prescribing Information before prescribing Dimple™, available on request from Mylan Pharmaceuticals Private Limited, 10th Floor, Prestige Platina, Block 3, Kadubeesanahalli Village, Varthur Hobli, Outer Ring Road, Bangalore 560 087