

## **Tiup® Cu 375**

Intrauterine Contraceptive Device

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

**Dosage and Administration:** Tiup® Cu 375 is intended for single use only and is advised to remove every 5 years. To be inserted by a skilled healthcare provider and use no-touch technique to ensure sterile handling. For complete description of the procedure please refer to the full prescribing information.

**Warning and precautions:** Tiup® Cu 375 is inserted after medical examination and should be used with precautions in nulliparous women and PID. IUDs do not protect against HIV infection and/or AIDS or any other sexually transmitted disease. Insertion of an IUD may precipitate a seizure in women suffering from epilepsy. Special care is therefore recommended during insertion. **Contraindications:** Malignant disease of the corpus uteri or cervix, vaginal bleeding of undiagnosed etiology, pregnancy (established or suspected), ectopic pregnancy or the presence of predisposing factors for this condition such as salpingitis, endometrial or pelvic peritonitis. Congenital or acquired malformations or distortions of the uterus or the cervix; large or multiple uterine fibromyomata in the presence of excessively heavy menstrual periods; endometrial hyperplasia; cervical dysplasia. Genital infection (with the exception of candidiasis), sexually transmitted disease during past 12 months (with the exception of bacterial vaginitis, candidiasis recurrent herpes virus infection, hepatitis B or cytomegalovirus infection). Infected abortion in the past 3 months, active pelvic inflammatory disease (PID) or history of recurrent PID and allergy to copper. **Interactions:** Corticosteroids, non-steroidal anti-inflammatory drugs, or immunosuppressive therapy and tetracyclines may reduce the contraceptive efficacy of copper-containing IUDs and women preferably should opt for another contraceptive method.

**Adverse Reactions:** After insertion uterine cramps and/or abdominal pain, syncope, bradycardia and other neuro-vascular episodes particularly in nulliparous. During the initial cycles breakthrough, bleeding and/or spotting, prolongation of menstruation and an increase in menstrual blood loss and dysmenorrhea. Other side effects include back pain, pains in the legs, dyspareunia, genito-urinary infections (e.g.PID), abnormal vaginal discharge, perforation of uterus or cervix, increased risk of spontaneous abortion and septicemia, ectopic pregnancy and urticarial allergic skin reaction.

**Composition:** Tiup® Cu 375 has flexible side-arms, made of polyethelene. A copper wire is wound around the stem, giving a total copper surface area of 375 mm<sup>2</sup>. A monofilament nylon thread is attached to the stem. The stem length is 35 mm and the width is 18 to 20 mm.

**Manufactured by:** Mylan Laboratories Ltd. An ISO 9001 & ISO 13485 Compliant Company)Plot No. 688/10 & 11, Siddhi Vinayak Industrial Estate,Somnath Road, Dabhel, Daman - 396 210, India.

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

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Please refer to the full Prescribing Information before prescribing Tiup® Cu 375 ,available on request from Mylan Pharmaceuticals Private Limited, 10th Floor, Prestige Platina, Block 3, Kadubeesanahalli Village, Varthur Hobli, Outer Ring Road, Bangalore 560 087