

NZ Abridged Product Information

MIRENA® (levonorgestrel)

MIRENA® is used for contraception, idiopathic menorrhagia and endometrial protection. Prescription Medicine. 52 mg intrauterine delivery system containing levonorgestrel.

Initial release rate 20 µg/24 hrs. **INDICATIONS:** Contraception, idiopathic menorrhagia and prevention of endometrial hyperplasia during oestrogen replacement therapy.

DOSAGE AND ADMINISTRATION: Insert into the uterine cavity. Up to 5 year *in-situ* life. Refer to Data Sheet for instructions on insertion and removal.

CONTRAINDICATIONS: Known/suspected pregnancy; current or recurrent pelvic inflammatory disease; lower genital tract infection; postpartum endometritis; infected abortion during the past three months; cervicitis, cervical dysplasia; uterine or cervical malignancy; progestogen dependent tumours; undiagnosed abnormal uterine bleeding; congenital or acquired uterine anomaly including fibroids if they distort the uterine cavity; conditions associated with increased infection susceptibility; acute liver disease/tumour; allergy to the constituents. **PRECAUTIONS:** Use with caution after specialist consultation or consider removal if following exist or arise for the first time: migraine,

focal migraine with asymmetrical visual loss or other symptoms indicating transient cerebral ischemia, exceptionally severe headache, jaundice, marked increase in blood pressure, severe arterial disease. Young nulligravid women; post-menopausal women with advanced uterine atrophy; venous thromboembolism; breast cancer; congenital or valvular heart disease; diabetes; oligomenorrhoea and/or amenorrhoea; lost threads; pelvic infections; expulsion; perforation; ectopic pregnancy; ovarian cysts. **Interactions:** CYP450 inducers e.g. anticonvulsants & anti-infectives. **ADVERSE EFFECTS:** headache, abdominal/pelvic pain, changes in menstrual bleeding, vulvovaginitis, genital discharge, depressed mood, nervousness, decreased libido, migraine, nausea, acne, hirsutism, back pain, upper genital tract infection, ovarian cyst, dysmenorrhoea, breast tenderness, breast pain, intrauterine contraceptive device expulsion, weight gain, cervicitis, uterine perforation. Others: refer to full Data Sheet.

MIRENA is funded for patients who meet the Heavy Menstrual Bleeding Criteria.

MIRENA is not funded for contraception or endometrial protection - a prescription charge will apply. Before prescribing, please review full Data Sheet for further information on the risks and benefits. Full Data Sheet is available from www.medsafe.govt.nz or Bayer New Zealand Limited, 3 Argus Place, Hillcrest North Shore Auckland 0627, telephone 0800 233 988