Prescribing Information Levosert 20 micrograms/24 hours Intrauterine Delivery System. Please refer to the Summary of Product Characteristics (SmPC) before prescribing. **Presentation:** Intrauterine delivery system (IUS) containing 52 mg levonorgestrel. **Indication(s):** Contraception. Treatment of heavy menstrual bleeding; Levosert may be particularly useful in women with heavy menstrual bleeding requiring (reversible) contraception. **Dosage and Administration:** A bimanual pelvic examination should be performed to establish the orientation of the uterus. Pregnancy should be excluded and genital infection should be successfully treated. In women of fertile age, Levosert is inserted into the uterine cavity within 7 days of the onset of menstruation. To reduce the risk of perforation, postpartum insertions should be postponed until the uterus is fully involuted and not earlier than 6 weeks after delivery. Levosert can be inserted immediately after a first trimester abortion. **Levosert is effective for 5 years and should be removed after 5 years of use.** If desired, a new system can be inserted at the same time. Consult the SmPC for full information on insertion and removal. Levosert has blue threads and the T-frame contains barium sulphate so that it can be seen on X-rays. **Contraindications:** Known or suspected pregnancy; current or recurrent pelvic inflammatory disease; lower genital infection; postpartum endometritis; infected abortion during the past three months; cervicitis, cervical dysplasia; suspected or confirmed uterine or cervical malignancy; liver tumour or other acute or severe liver disease; congenital or acquired abnormality of the uterus including fibroids if they distort the uterine cavity; undiagnosed abnormal uterine bleeding; conditions associated with increased susceptibility to infections; current or suspected hormone dependent tumours such as breast cancer; acute malignancies affecting the blood or leukaemias except when in remission; recent trophoblastic disease while hCG levels remain elevated; hypersensitivity to the active substance or to any of the excipients. **Warnings and Precautions:** Before insertion, a complete personal and family medical history should be taken. Pulse and blood pressure should be measured and a bimanual pelvic examination performed to establish the orientation of the uterus. Re-examine six weeks after insertion and where clinically indicated. Use with caution or consider removal if any of the following conditions exist or arise for the first time during treatment: migraine, focal migraine with asymmetrical visual loss or other symptoms indicating transient cerebral ischemia; unusually severe or frequent headache; jaundice; marked increase of blood pressure; malignancies affecting the blood or leukaemias in remission; use of chronic corticosteroid therapy; past history of symptomatic functional ovarian cysts; active or previous severe arterial disease, such as stroke or myocardial infarction; severe or multiple risk factors for arterial disease; thrombotic arterial or any current embolic disease; acute venous thromboembolism; congenital heart disease or valvular heart disease at risk of infective endocarditis; irregular bleedings as these may mask some symptoms and signs of endometrial polyps or cancer. Women should be encouraged to stop smoking. Depression and depressed mood are well known undesirable effects of hormonal contraceptives. Advise women to contact their physician in case of mood changes, depressive symptoms or suicidal thoughts. **Insertion/removal** may be associated with some pain and bleeding and may result in fainting as a vasovagal reaction or seizure in epileptics. In cases of severe pain and continued bleeding during or after insertion, exclude perforation of the uterine corpus or cervix. If perforation is suspected the system should be removed. Risk of perforation may be increased in post-partum insertions, in lactating women and in women with a fixed retroverted uterus. If pelvic infection is suspected, appropriate antibiotics should be started.

Remove Levosert, if the woman experiences recurrent endometritis, pelvic infection or if an acute infection is severe. The woman should be advised on how to check the Levosert threads and to immediately see her doctor if she cannot feel the threads. If the threads cannot be found, first exclude pregnancy. They may have broken off, the system may have been expelled, or rarely the device may be extra-uterine after having perforated the uterus. An ultrasound should be arranged and alternative contraception should be advised in the meantime. If an ultrasound cannot locate the device and there is no evidence of expulsion, a plain abdominal X-ray should be performed to exclude an extra-uterine device. Symptoms of partial or complete expulsion of the IUS may include bleeding or pain. Increased menstrual flow may be indicative of expulsion. If menorrhagia persists, an assessment of the uterine cavity using ultrasound scan should be performed and endometrial biopsy considered. Irregular bleeding/spotting may occur during the first months of therapy in pre-menopausal women therefore endometrial pathology should be excluded before insertion. The possibility of pregnancy should be considered and expulsion excluded if menstruation does not occur within six weeks of the onset of previous menstruation. In menorrhagia, if significant reduction in menstrual blood loss is not achieved within 3 to 6 months, alternative treatments should be considered. The possibility of ectopic pregnancy should be considered in the case of lower abdominal pain - especially in connection with missed periods or if an amenorrhoeic woman starts bleeding. Women with a previous history of ectopic pregnancy, tubal surgery or pelvic infection carry an increased risk of ectopic pregnancy. Ovarian cysts have been reported. Most of these follicles are asymptomatic, although some may be accompanied by pelvic pain or dyspareunia. If ovarian cysts do not disappear spontaneously during two to three months observation, continued ultrasound monitoring and other diagnostic/therapeutic measures are recommended. Some studies suggest a slightly increased relative risk of breast cancer in women using combined oral contraceptives (COC). The risk may be of similar magnitude for progestogen-only methods such as Levosert but the evidence is based on much smaller population of users and so is less conclusive. Blood glucose concentrations should be monitored in diabetic patients. Levosert should not be used as a post-coital contraceptive. **Interactions:** Metabolism of progestogens may be affected by concomitant use of inducers or inhibitors of drug-metabolising enzymes, specifically cytochrome P450 enzymes. The influence of these drugs on the contraceptive efficacy of Levosert is not known but it is not believed to be of major importance due to the local mechanism of action. **Fertility, Pregnancy & Lactation:** Should not be used during an existing or suspected pregnancy. If pregnancy occurs with Levosert in situ, ectopic pregnancy should be excluded, the system removed and termination of the pregnancy considered. Removal or probing of the uterus may result in spontaneous abortion. If removal is not possible or if the woman wishes to continue the pregnancy, the pregnancy should be monitored closely and the woman should be informed about the risks and instructed to report all symptoms suggesting complications, like cramping abdominal pain with fever. Due to intrauterine administration and local exposure to hormone, the possible occurrence of virilising effects in the foetus should be taken into consideration. Levonorgestrel is excreted in very small quantities in breast milk and breast feeding can be continued during use. Uterine bleeding has been reported rarely during lactation. The use of levonorgestrel IUS does not alter the course of female fertility after the removal of the IUS. **Undesirable Effects:** *Very common*: uterine/vaginal bleeding including spotting, oligomenorrhoea, amenorrhoea; vaginal bacterial infections, vulvovaginal mycotic infections; procedural pain and bleeding; acne; benign ovarian cysts. *Common*: depressive mood, nervousness, decreased libido; headache, migraine, presyncope; abdominal pain/discomfort, abdominal distension, nausea, vomiting; back pain; pelvic pain, dysmenorrhoea, dyspareunia, uterine spasm; vaginal discharge, vulvovaginitis, breast tenderness, breast pain; IUS expulsion; weight increase. *Uncommon*: syncope; alopecia, hirsutism, pruritus, eczema, chloasma/skin hyperpigmentation; pelvic inflammatory disease, endometritis, cervicitis, Papanicolaou smear normal, class II; ectopic pregnancy; uterine perforation; oedema. *Rare*: Hypersensitivity including rash, urticaria, angioedema. Consult SmPC in relation to other adverse reactions. **Legal Category:** POM. **Pack Size and NHS Price:** Each pack contains one Levosert - £66.00. **Marketing Authorisation Number:** PL 04854/0158. **Marketing Authorisation Holder:** Gedeon Richter Plc., Gyömrői út 19-21, 1103 Budapest, Hungary. **Further information is available from:** Gedeon Richter UK Ltd, 127 Shirland Road, London W9 2EP. Tel: +44 (0) 207 604 8806.

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Women's Health Division of Gedeon Richter (UK) Ltd on +44 (0) 207 604 8806 or drugsafety.uk@gedeonrichter.e