

Prescribing Information Emergency Contraceptive Richter 1500 microgram tablet

Presentation: Emergency Contraceptive Richter 1500 microgram tablet

Indications: Emergency contraception within 72 hours of unprotected sexual intercourse or failure of a contraceptive method.

Dosage and administration: One tablet should be taken orally, as soon as possible, preferably within 12 hours, and no later than 72 hours after unprotected intercourse. If vomiting occurs within three hours of taking the tablet, another tablet should be taken immediately. Women who have used enzyme-inducing drugs during the last 4 weeks and need emergency contraception (EC) are recommended to use a non-hormonal EC, i.e. Cu-IUD or take a double dose of levonorgestrel (i.e. 2 tablets taken together) for those women unable or unwilling to use Cu-IUD. Taking a double dose of levonorgestrel (i.e. 3000 mcg within 72 hours after the unprotected intercourse) is an option for women who are unable or unwilling to use a Cu-IUD, although this specific combination (a double dose of levonorgestrel during concomitant use of an enzyme inducer) has not been studied. Emergency Contraceptive Richter can be used at any time during the menstrual cycle unless menstrual bleeding is overdue. After using EC, it is recommended to use a local barrier method until the next menstrual period starts. The use of levonorgestrel does not contraindicate the continuation of regular hormonal contraception.

Contraindications: Hypersensitivity to levonorgestrel or to any of the excipients

Warnings and precautions: EC is an occasional method. It should in no instance replace a regular contraceptive method. Women who present for repeated courses of EC should be advised to consider and initiate long-term methods of contraception. Repeated administration within a menstrual cycle is not advisable because of the possibility of disturbance of the cycle. EC does not prevent a pregnancy in every instance. If there is uncertainty about the timing of the unprotected intercourse or if the woman has had unprotected intercourse more than 72 hours earlier in the same menstrual cycle, conception may have occurred. Treatment with levonorgestrel following the second act of intercourse may therefore be ineffective in preventing pregnancy. If menstrual periods are delayed by more than 5 days or abnormal bleeding occurs at the expected date of menstrual periods or pregnancy is suspected for any other reason, pregnancy should be excluded. If pregnancy occurs after treatment with levonorgestrel, the possibility of an ectopic pregnancy should be considered. The absolute risk of ectopic pregnancy is likely to be low, as levonorgestrel prevents ovulation and fertilisation. Ectopic pregnancy may continue, despite the occurrence of uterine bleeding. Therefore, levonorgestrel is not recommended for patients who are at risk of ectopic pregnancy (previous history of salpingitis or of ectopic pregnancy). Levonorgestrel is not recommended in patients with severe hepatic dysfunction. Severe malabsorption syndromes, such as Crohn's disease, might impair the efficacy of levonorgestrel. After levonorgestrel intake, menstrual periods are usually normal and occur at the expected date. They can sometimes occur earlier or later than expected by a few days. If no withdrawal bleed occurs in the next pill-free period following the use of levonorgestrel after regular hormonal contraception, pregnancy should be ruled out. Limited and inconclusive data suggest that there may be reduced efficacy of Emergency Contraceptive Richter with increasing body weight or body mass index (BMI). In all women, EC should be taken as soon as possible after unprotected intercourse, regardless of the woman's body weight or BMI. EC does not replace the necessary precautions against sexually transmitted diseases. Contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Interactions: Levonorgestrel metabolism is enhanced by concomitant use of liver enzyme inducers, mainly CYP3A4 enzyme inducers. Concomitant administration of efavirenz has been found to reduce plasma levels of levonorgestrel (AUC) by around 50%. Drugs suspected of having similar capacity to reduce plasma levels of levonorgestrel include barbiturates (including primidone), phenytoin, carbamazepine, herbal medicines containing *Hypericum perforatum* (St. John's Wort), rifampicin, ritonavir, rifabutin, and griseofulvin. Levonorgestrel may increase the risk of ciclosporin toxicity due to possible inhibition of ciclosporin metabolism.

Fertility, Pregnancy and Lactation: Levonorgestrel should not be given to pregnant women. It will not interrupt a pregnancy. In the case of continued pregnancy, limited epidemiological data indicate no adverse effects on the foetus but there are no clinical data on the potential consequences if doses greater than 1.5 mg of levonorgestrel are taken. Levonorgestrel is secreted into breast milk. Potential exposure of an infant to levonorgestrel can be reduced if the breast-feeding woman takes the tablet immediately after feeding and avoids nursing at least 8 hours following levonorgestrel administration. Levonorgestrel increases the possibility of cycle disturbances which can sometimes lead to earlier or later ovulation date. These changes can result in modified fertility date, however, there are no fertility data in the long term.

Undesirable effects: *Very Common:* headache, nausea, abdominal pain lower, bleeding not related to menses, fatigue. *Common:* dizziness, diarrhoea, vomiting, delay of menses more than 7 days, menstruation irregular, breast tenderness. *Very rare:* face oedema. **Please consult SmPC in relation to other adverse events**

Legal category: P

Pack size and NHS price: One tablet £13.83 excluding VAT

Marketing Authorization Number: PL 04854/0105. **Date of Authorisation:** 15 Feb 2012.

Marketing Authorization Holder: Gedeon Richter Plc. Gyömrői út 19-21, H-1103 Budapest Hungary. Further information available from: Gedeon Richter UK Ltd, 127 Shirland Road, London W9 2EP. Tel: +44 (0) 207 604 8806. Email: medinfo.uk@gedeonrichter.eu

Date of Preparation: 29 April 2020

Adverse events should be reported. Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk/>. Adverse events should also be reported to Gedeon Richter (UK) Ltd on +44 (0) 207 604 8806 or drugsafety.uk@gedeonrichter.eu

Prescribing Information Upostelle

Presentation: Upostelle (levonorgestrel)1500 microgram tablets

Indications: Emergency contraception within 72 hours of unprotected sexual intercourse or failure of a contraceptive method.

Dosage and administration: One tablet should be taken orally, as soon as possible, preferably within 12 hours, and no later than 72 hours after unprotected intercourse. If vomiting occurs within three hours of taking the tablet, another tablet should be taken immediately. Women who have used enzyme-inducing drugs during the last 4 weeks and need emergency contraception (EC) are recommended to use a non-hormonal EC, i.e. Cu-IUD or take a double dose of levonorgestrel (i.e. 2 tablets taken together) for those women unable or unwilling to use Cu-IUD. Taking a double dose of levonorgestrel (i.e. 3000 mcg within 72 hours after the unprotected intercourse) is an option for women who are unable or unwilling to use a Cu-IUD, although this specific combination (a double dose of levonorgestrel during concomitant use of an enzyme inducer) has not been studied. Upostelle can be used at any time during the menstrual cycle unless menstrual bleeding is overdue. After using EC, it is recommended to use a local barrier method until the next menstrual period starts. The use of levonorgestrel does not contraindicate the continuation of regular hormonal contraception.

Contraindications: Hypersensitivity to levonorgestrel or to any of the excipients

Warnings and precautions: EC is an occasional method. It should in no instance replace a regular contraceptive method. Women who present for repeated courses of EC should be advised to consider and initiate long-term methods of contraception. Repeated administration within a menstrual cycle is not advisable because of the possibility of disturbance of the cycle. EC does not prevent a pregnancy in every instance. If there is uncertainty about the timing of the unprotected intercourse or if the woman has had unprotected intercourse more than 72 hours earlier in the same menstrual cycle, conception may have occurred. Treatment with levonorgestrel following the second act of intercourse may therefore be ineffective in preventing pregnancy. If menstrual periods are delayed by more than 5 days or abnormal bleeding occurs at the expected date of menstrual periods or pregnancy is suspected for any other reason, pregnancy should be excluded. If pregnancy occurs after treatment with levonorgestrel, the possibility of an ectopic pregnancy should be considered. The absolute risk of ectopic pregnancy is likely to be low, as levonorgestrel prevents ovulation and fertilisation. Ectopic pregnancy may continue, despite the occurrence of uterine bleeding. Therefore, levonorgestrel is not recommended for patients who are at risk of ectopic pregnancy (previous history of salpingitis or of ectopic pregnancy). Levonorgestrel is not recommended in patients with severe hepatic dysfunction. Severe malabsorption syndromes, such as Crohn's disease, might impair the efficacy of levonorgestrel. After levonorgestrel intake, menstrual periods are usually normal and occur at the expected date. They can sometimes occur earlier or later than expected by a few days. If no withdrawal bleed occurs in the next pill-free period following the use of levonorgestrel after regular hormonal contraception, pregnancy should be ruled out. Limited and inconclusive data suggest that there may be reduced efficacy of Upostelle with increasing body weight or body mass index (BMI). In all women, EC should be taken as soon as possible after unprotected intercourse, regardless of the woman's body weight or BMI. EC does not replace the necessary precautions against sexually transmitted diseases. Contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

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Undesirable effects: *Very Common:* headache, nausea, abdominal pain lower, bleeding not related to menses, fatigue. *Common:* dizziness, diarrhoea, vomiting, delay of menses more than 7 days, menstruation irregular, breast tenderness. *Very rare:* face oedema. **Please consult SmPC in relation to other adverse events**

Legal category: POM

Pack size and NHS price: One tablet £3.75

Marketing Authorization Number: PL 04854/0106. **Date of Authorisation:** 15 Feb 2012.

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