Ryeqo® abbreviated SmPC

Ryeqo® 40 mg/1 mg/0.5 mg film-coated tablets. **Active ingredients:** relugolix, estradiol, norethisterone acetate. **Composition:** Each film-coated tablet contains 40 mg of relugolix, 1 mg of estradiol (as hemihydrate), and 0.5 mg of norethisterone acetate. **Other ingredients:** Lactose monohydrate, mannitol, sodium poly starch glycolate, hydroxypropylcellulose, magnesium stearate, hypromellose type 2910, titanium dioxide, triacetin, iron oxide yellow. **Indications:** For adult women of reproductive age for the treatment of moderate to severe symptoms of uterine fibroids and for the symptomatic treatment of endometriosis in women with a history of previous medical or surgical treatment for their endometriosis. **Contraindications:** Hypersensitivity to the active substance(s) or to any of the excipients, venous thromboembolic disorder, past or present (e.g. deep venous thrombosis, pulmonary embolism), arterial thromboembolic cardiovascular disease, past or present (e.g. myocardial infarction, cerebrovascular accident, ischemic heart disease), known thrombophilic disorders (e.g. protein C, protein S or antithrombin deficiency or activated protein C (APC) resistance, including Factor V Leiden), known osteoporosis, headaches with focal neurological symptoms or migraine headaches with aura, known or suspected sex steroid influenced malignancies (e.g. of the genital organs or the breasts), presence or history of liver tumours (benign or malignant), presence or history of severe hepatic disease as long as liver function values have not returned to normal, pregnancy or suspected pregnancy and breastfeeding, genital bleeding of unknown aetiology, concomitant use of hormonal contraceptives. **Side effects:** *Very common*: headache, hot flush *Common*: irritability, libido decreased, dizziness, nausea, alopecia, hyperhidrosis, night sweats, arthralgia, uterine bleeding, vulvovaginal dryness *Uncommon*: dyspepsia, breast cyst, uterine myoma expulsion, angioedema, urticaria. **Warnings:** Prescription only. Ryeqo® treatment should be initiated and supervised by a physician experienced in the diagnosis and treatment of uterine fibroids and/or endometriosis. Contains lactose. **Marketing Authorization Holder:** Gedeon Richter Plc., Gyömrői út 19-21., 1103 Budapest, Hungary. **Adverse event reporting:** Pharmacovigilance Department at Gyömrői út 19-21., 1103 Budapest, Hungary. Phone: +36-1-505-7032 E-mail: drugsafety@richter.hu. Online adverse event reporting: https://richter.link/aer. Information current as of March 2026.