REGESTRONE LX

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for REGESTRONE LX [Relugolix, Estradiol and Norethindrone Acetate Tablets (40 mg + 1 mg + 0.5 mg)]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: ***Relugolix*** is a non-peptide GnRH receptor antagonist that binds to and inhibits GnRH receptors in the anterior pituitary gland. In humans, inhibition of GnRH receptor results in a dose dependent decrease in the release of luteinizing hormone (LH) and follicle-stimulating hormone (FSH) from the anterior pituitary gland. As a result, circulating concentrations of LH and FSH are reduced. The reduction in FSH concentrations prevents follicular growth and development, thereby reducing the production of estrogen. Prevention of an LH surge inhibits ovulation and development of the corpus luteum, which precludes the production of progesterone. Therefore, Relugolix Estradiol & Norethisterone provides adequate contraception when taken for at least 1 month. ***Estradiol*** is the same as the endogenously produced hormone and is a potent agonist of the nuclear estrogen receptor (ER) subtypes. Exogenously administered estradiol alleviates symptoms associated with a hypoestrogenic state, such as vasomotor symptoms and bone mineral density loss. ***Norethisterone acetate*** is a synthetic progestogen. As estrogens promote the growth of the endometrium, unopposed estrogens increase the risk of endometrial hyperplasia and cancer. The addition of a progestogen reduces the estrogen-induced risk of endometrial hyperplasia in non-hysterectomised women.

INDICATIONS: Indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women.

DOSAGE AND ADMINISTRATION: The recommended dose is 1 tablet once daily or as directed by the Physician.

CONTRAINDICATION: 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.

WARNINGS & PRECAUTIONS: Conditions such as gallbladder disease, cholelithiasis and cholecystitis have been reported to occur or worsen with estrogen and progestogen use, including Relugolix, Estradiol & Norethisterone, but the evidence of an association with Relugolix Estradiol & Norethisterone is inconclusive. Submucosal uterine fibroids are common (15% to 20% of women with uterine fibroids) and some may prolapse through the cervix or be expelled, sometimes with transient worsening of uterine bleeding.

DRUG INTERACTIONS: Medicinal products that inhibit the activity of hepatic drug-metabolising enzymes, e.g. ketoconazole, may increase circulating concentrations of the estrogen and norethisterone components in Relugolix Estradiol & Norethisterone. Estrogen and

progestogen medicinal products may affect the metabolism of certain other active substances. Accordingly, plasma concentrations may either increase (e.g. cyclosporin) or decrease (e.g. lamotrigine) with use of Relugolix Estradiol & Norethisterone. Dose adjustment of these medicinal products may be necessary.

ADERVSE REACTIONS: Irritability, hot flush, dyspepsia, alopecia, hyperhidrosis night, sweats, angioedema, urticaria, uterine bleeding, breast cyst, libido decreased, uterine myoma expulsion

MARKETED BY:

TORRENT PHARMA

Torrent Pharmaceuticals Limited.

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(Additional information is available on request)