Renorma®

Tibolone

Composition
Renorma® Tablet: Each tablet contains Tibolone BP 2.50 mg.

Pharmacology
Tibolone is a synthetic steroid that has estrogenic, androgenic and progestagenic properties. After oral administration, Tibolone is rapidly metabolized into three compounds which contribute to the pharmacological effects of Tibolone. Two of these metabolites (the 3α–OH and 3β–OH metabolite) have predominantly estrogenic activity; a third metabolite (δ4-isomer of Tibolone) and the parent compound have predominantly progestagenic and androgenic activities. Tibolone substitutes for the loss of estrogen production in postmenopausal women and alleviates menopausal symptoms. It prevents bone loss following menopause or ovariectomy. It has estrogenic effects on the vagina, on bone and on the thermoregulatory centers in the brain (hot flushes). It improves vaginal dryness and vaginal atrophy. Tibolone has also effects on mood and libido.

Indication
- Treatment of symptoms resulting from the natural or surgical menopause in post menopausal women.
- Prevention of osteoporosis in women who have gone through the menopause and are at high risk of fractures, but cannot take other medicines used to prevent osteoporosis.

Dosage and Administration
Treatment of symptoms resulting from the natural or surgical menopause:
The recommended dose is 2.50 mg once daily.

Prevention of post-menopausal bone mineral density loss:
The recommended dose is 2.50 mg once daily.

Improvement of symptoms generally occurs within a few weeks, but optimal results are obtained when therapy is continued for at least 3 months. Review should be needed for continuation of treatment after 6 months, taking into account the risk-benefit ratio for the individual user at that moment.

Starting Renorma®
Women experiencing a natural menopause should commence treatment with **Renorma**® at least 12 months after their last natural bleed. In case of a surgical menopause, treatment with **Renorma**® may commence immediately.

Switching from combined / oestrogen only hormone replacement therapy (HRT)
In women with a uterus who change from an oestrogen-only preparation, a withdrawal bleed should be induced before starting **Renorma**®. If changing from a sequential HRT preparation, treatment with Tibolone should be started after the progestagen phase has been completed. If changing from a continuous-combined HRT preparation, treatment can be started at any time. If abnormal vaginal bleeding is the reason for switching from combined HRT, it is advised to investigate the cause of bleeding before starting **Renorma**®.

Missed tablets
A missed dose should be taken as soon as remembered, unless it is more than 12 hours overdue. In the latter case, the missed dose should be skipped and the next dose should be taken at the normal time. Missing a dose may increase the likelihood of breakthrough bleeding and spotting.

As for all steroids with hormonal activity, yearly medical examination particularly of the breasts and pelvic areas is advisable. A review should be needed for continuation of treatment after 6 months.

Contraindication
- Pregnancy and lactation
- Known past or suspected breast cancer
- Known or suspected estrogen dependent malignant tumours (e.g. endometrial cancer)
- Undiagnosed genital bleeding
- Untreated endometrial hyperplasia
- Previous idiopathic or current venous thromboembolism (deep venous thrombosis, pulmonary embolism)
- Any history of arterial thromboembolic disease (e.g. angina, myocardial infarction, stroke or TIA)
- Acute liver disease or a history of liver disease as long as liver function tests have failed to return to normal.
- Known hypersensitivity to the active substance or any of the excipients
- Porphyria

Precautions
- Leiomyoma (uterine fibroids) or endometriosis
- A history of, or risk factors for, thromboembolic disorders
- Risk factors for oestrogen dependent tumors, e.g. 1st degree heredity for breast cancer
- Hypertension
- Liver disorders (e.g. liver adenoma)
- Diabetes mellitus with or without vascular involvement
- Cholelithiasis
- Migraine or (severe) headache
- Systemic lupus erythematosis
- A history of endometrial hyperplasia
- Epilepsy
- Asthma
- Osteosclerosis

Reasons for Immediate Withdrawal of Therapy:
Therapy should be discontinued in case a contraindication is discovered and in the following situations:
- Jaundice or deterioration in liver function
- Significant increase in blood pressure
- New onset of migraine-type headache

Use in Pregnancy
USFDA pregnancy category D.

Use in Lactation
Tibolone is contraindicated in lactating women.

Interaction with other Medicines
Since Tibolone may increase blood fibrinolytic activity, it may enhance the effect of anticoagulants. This effect has been demonstrated with warfarin. Therefore, the simultaneous use of Tibolone and warfarin should be monitored, especially when starting or stopping concurrent Tibolone treatment, and the warfarin dose should be appropriately adjusted.

Adverse Reactions
Gastrointestinal disorders like abdominal pain, skin and subcutaneous tissue disorders like abnormal hair growth, acne, reproductive system and breast disorders like vaginal discharge, endometrial hypertrophy, postmenopausal haemorrhage, breast tenderness, genital pruritus, vaginal candidiasis, cervical dysplasia etc.

Overdose
The acute toxicity of Tibolone in animals is very low. Therefore, toxic symptoms are not expected to occur if several tablets are taken simultaneously. In cases of acute overdose - nausea, vomiting, and withdrawal bleeding in females may develop. Symptomatic treatment can be given if necessary.

Storage Condition
Store in a dry & cool place, protected from light & moisture.

How Supplied
Renorma® Tablet : Each box contains 30 tablets.

Manufactured by :
SQUARE
PHARMACEUTICALS LTD.
BANGLADESH

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