Tibonor®

Tibolone BP tablet

DESCRIPTION

Tibonor® is a preparation of Tibolone BP. 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 3a-OH and 3b-OH metabolite) have predominantly estrogenic activity; a third metabolite (D^4-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 centres in the brain (hot flushes). It improves vaginal dryness and vaginal atrophy. Tibolone has also effects on mood and libido.

INDICATIONS AND USES

- Treatment of symptoms (hot flushes, sweating, vaginal dryness and less elasticity, mood disorders, anxiety etc) resulting from the natural or surgical menopause in postmenopausal women.
- Prevention of bone mineral density loss in postmenopausal women at high risk of future osteoporotic fractures who are intolerant of, or contraindicated for, other medicinal products approved for the prevention of bone mineral density loss.

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. The need for continuation of treatment should be reviewed after 6 months taking into account the risk-benefit ratio for the individual user at that moment.

Starting Tibonor®
Women experiencing a natural menopause should commence treatment with **Tibonor®** at least 12 months after their last natural bleed. In case of a surgical menopause, treatment with **Tibonor®** 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 **Tibonor®**. 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 anytime. If abnormal vaginal bleeding is the reason for switching from combined HRT, it is advised to investigate the cause of bleeding before starting **Tibonor®**.

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.

Monitoring Advice
As for all steroids with hormonal activity, yearly medical examination particularly of the breasts and pelvic areas is advisable. Review the need for continuation of treatment after 6 months.

CONTRAINDICATIONS

- 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

SIDE-EFFECTS

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

USE IN PREGNANCY & LACTATION

Pregnancy: Pregnancy category D.
Lactation: Tibolone is contraindicated in lactating women.

DRUG INTERACTIONS

Since Tibolone may increase blood fibrinolytic activity, it may enhance the effect of anticoagulants. This effect has been reported with warfarin.

PRECAUTIONS

Conditions which need supervision during treatment with tibolone: 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.

OVERDOSAGE

The acute toxicity of Tibolone in animals is very low. Therefore, toxic symptoms are not expected to occur, even when several tablets are taken simultaneously. In case of acute overdose nausea, vomiting, withdrawal bleeding etc. may occur. Symptomatic treatment can be given if necessary.

PHARMACEUTICAL PRECAUTION

Keep away from light, store below 30°C temperature & in a dry place. Keep out of reach of children.

PACKAGING

Tibonor® Tablet: Box containing 3 strips of 10 tablets each. Each tablet contains Tibolone BP 2.5 mg.

SK+F
Manufactured for
ESKAYEF BANGLADESH LIMITED
By POPULAR PHARMACEUTICALS LTD.
GAZIPUR, BANGLADESH
® REGD.TRADEMARK
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