

# Tivion®

Tibolone

## Description

**Tivion®** is a preparation of Tibolone which is a synthetic steroid that mimics the activity of the female sex hormones oestrogen and progesterone and the androgen testosterone in the body. Tibolone is a unique chemical compound for postmenopausal women experiencing symptoms due to lack of oestrogen. It is a synthetic hormone, alternative to conventional Hormone Replacement Therapy (HRT) that helps to restore hormonal balance and prevents osteoporosis in postmenopausal women. Tibolone is a STEAR (Selective Tissue Estrogenic Activity Regulator) that acts like oestrogen in the brain (preventing flushes), bone (preventing bone loss) and vaginal tissue (preventing dryness and soreness). It acts like progesterone in the womb to prevent overgrowth of the endometrium and subsequent bleeding. The testosterone like activity of Tibolone plays a role in enhancing women's mood and libido. In postmenopausal women, Tibolone is effective on bone, vagina, climacteric symptoms, mood and sexual well being, without stimulating endometrium or breast.

## Indication and usage

**Tivion®** can be used-

- Primarily for treatment of climacteric symptoms and prevention of osteoporosis in postmenopausal women
- For women who had hysterectomy and experiencing menopausal symptoms
- For women being treated with Gonadotropin Releasing Hormone (GnRH) analogues, such as for endometriosis

## Dosage and administration

The usual dose is 1 tablet (2.5 mg) once daily, preferably at the same time every day. If a dose is missed, take it as soon as remembered unless it is more than 12 hours late. If it is more than 12 hours, leave the missed dose. Do not take two doses together to make up for a forgotten dose.

## Use in pregnancy and lactation

Tibolone is contraindicated during pregnancy. If pregnancy occurs during medication with Tibolone, treatment should be withdrawn immediately. Tibolone is contraindicated during lactation.

## Side effects

The common side effects of Tibolone are abdominal or pelvic pain, weight changes, abnormal hair growth, vaginal discharge and irritation. Also, there may be headache, dizziness, nausea, swollen feet and itching, breast tenderness. Vaginal bleeding or spotting may occur but this is uncommon.

## Precautions

Tibolone should be used cautiously in patients with history of liver disease, epilepsy, migraine, diabetes mellitus, hypercholesterolaemia. In case of vaginal bleeding, investigate for endometrial cancer if bleeding continues beyond six months or after stopping treatment. Withdraw if there are signs of thromboembolic disease, abnormal liver function tests or cholestatic jaundice.

## Contraindications

Tibolone is contraindicated in known hypersensitivity to Tibolone or any of the excipients of the drug. It is also contraindicated in women with known, past or suspected breast cancer, known or suspected oestrogen-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, porphyria. It should not be taken in combination with other hormone therapy and with testosterone.

## Drug interaction

Tibolone may increase blood fibrinolytic activity, so it may enhance the effect of anticoagulants like warfarin. Tibolone affects pharmacokinetics of the cytochrome P450 3A4 substrate midazolam to a moderate extent.

## 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 cases of acute overdose, nausea, vomiting and vaginal bleeding in females may occur. No specific antidote is known. Symptomatic treatment can be given if necessary.

## Pharmaceutical precautions

Store in a cool and dry place. Protect from light. Keep away from the reach of children.

## Presentation

**Tivion**<sup>®</sup> tablet: Each tablet contains Tibolone BP 2.5 mg.

## Package quantities

**Tivion**<sup>®</sup> tablet: Carton of 30 tablets in blister pack.

® Registered Trade Mark



Manufactured for

**ACI Limited**

Narayanganj, Bangladesh

by Popular Pharmaceuticals Ltd.