

TIBOLONE 2.5MG TAB

Class: Estrogen and Progestin Combination(synthetic steroid hormone)

Indications: Prevention of postmenopausal osteoporosis; symptomatic treatment of hot flushes and associated sweating resulting from menopause (surgical or natural); improvement of bone mineral density in patients with established postmenopausal osteoporosis

Available dosage form in the hospital:

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Dosage:

-Symptoms associated with menopause: Females: Oral: 2.5 mg once daily. Initiate ≥ 1 year after naturally occurring menopause, or immediately in women with surgical menopause or those being treated with gonadotropin releasing hormone (GnRH) analogues. **Note:** Use caution in women >60 years of age due to increased stroke risk

-Switching from other hormone replacement therapy (HRT): If on sequential HRT, initiate tibolone 1 day after the completion of the current treatment cycle. If on continuous-combined HRT, may initiate tibolone therapy immediately. **Note:** A separate progestogen should not be added to tibolone.

-Missed dose: If >12 hours has elapsed, skip dose and resume at next regularly scheduled time.

-Osteoporosis prophylaxis in postmenopausal women (unlabeled use in some countries): Oral: 2.5 mg once daily (Bundred, 2012; Roux, 2002). **Note:** In women >60 years of age, an increased risk of stroke was reported when taking 1.25 mg daily (Cummings, 2008).

Geriatric

Refer to adult dosing. Use caution in women >60 years of age due to increased stroke risk.

Renal Impairment:

No dosage adjustment provided in manufacturer's labeling; use with caution (may increase risk of fluid retention).

Hepatic Impairment:

Use is contraindicated in acute or chronic liver disease.

Common side effect: Common side effects observed in clinical studies (occurring in 1-10% of the women using Livial) were:

vaginal bleeding or spotting

abdominal pain

weight gain

breast pain

unnatural hair growth

vaginal symptoms, such as discharge, itching, and

Pregnancy Risk Factor: D (Adverse events have been observed in animal reproduction studies; use is contraindicated during pregnancy).