



# Tibolone for post-menopausal women

Tibolone is a type of hormone therapy (HT) designed to relieve menopausal symptoms and prevent osteoporosis (thinning of the bones) in post-menopausal women.

## What is tibolone?

- Tibolone is a synthetic steroid hormone derived from the Mexican yam
- The metabolites of tibolone have estrogenic, androgenic and progestogenic effects [1,2].
- Tibolone has oestrogen-like effects in the brain (preventing flushes), bone (preventing bone loss) and vaginal tissue (preventing dryness and soreness) [3,4].
- Tibolone also has progesterone-like effects at the uterus to prevent endometrial thickening and subsequent bleeding. A woman who has not had a hysterectomy does not need to take a progestogen if she is taking tibolone.
- Tibolone has testosterone-like activity that appears to play a role in enhancing women's mood and libido, although response is variable.

### When to commence tibolone

- Tibolone is suitable for women who have not experienced a natural period for at least 1 year. If taken sooner, irregular bleeding may be experienced.
- Usually a woman using cyclical HT and experiencing a monthly bleed can start tibolone after the oestrogen/progesterone phase of her current HT.
- Postmenopausal women not currently taking HT, or who have had a hysterectomy, may start at any time.
- A woman taking HT that contains the same amount of oestrogen and progestogen every day of the month can change to Tibolone at any time.

#### Side-effects of tibolone

- Side-effects are uncommon but may include headache, dizziness, nausea, abdominal pain, swollen feet and itching. Breast tenderness is also uncommon..
- Slight bleeding or spotting may commonly occur initially but tends to subside after a few months. Amenorrhea is achieved by about 80% of women after the first month of treatment with tibolone and over 90% after the third month of therapy [4].

# Long-term health

- Tibolone prevents bone loss and reduces spinal fractures [5].
- One uncontrolled English study has suggested that tibolone increases breast cancer risk but better quality
  placebo controlled randomised trials do not show that breast cancer rates in healthy women are changed by
  tibolone [5].
- Tibolone does not increase breast density [6].

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## Information Sheet

- Tibolone may interfere with the effectiveness of breast cancer therapies and its use is contraindicated in women with breast cancer [7].
- Regular mammograms and breast examination are advisable for all women.
- Tibolone decreases total and LDL cholesterol and triglyceride levels. However, it also decreases HDL cholesterol. The impact of these changes are not clear.
- Recent research suggests that Tibolone increases the risk of stroke [5]. This risk is mainly seen in women over 60 years of age. The increase among women in their 50s is 4 extra cases per 1000 and among women in their 60s, an extra 13 cases per 1000 women.
- Tibolone should not be used for cardiovascular protection.
- Few data are available with regard to thrombosis risk are available and the outcomes are inconclusive.

# **Key Points**

- Tibolone acts as a combined oral hormone therapy for treating menopausal symptoms.
- It has not been researched as extensively as some other forms of HT.
- Risks vs benefits for an individual need to take into account their co-morbidities.
- It is contraindicated in women who have had breast cancer.

#### References

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