

A photograph of a young woman with blonde hair and green eyes, wearing a blue denim shirt, lying on her back on a bed and smiling broadly. In the background, a man with a beard is lying on his back, looking towards the camera. The setting is a bright, airy room with a patterned pillow on the bed.

<sup>c</sup>Tibella<sup>®</sup>  
and you.

 BioSyent

<sup>c</sup>Tibella<sup>®</sup>  
(tibolone 2.5 mg tablets)

# <sup>c</sup>Tibella®

Your doctor has prescribed Tibella® for you. This booklet will give you an overview of menopause and taking Tibella®.

This information will help you understand the role of Tibella® in helping you manage your symptoms, such as hot flashes, flushing, and night sweats after menopause.

Please read it thoroughly before you start taking your medication. If you have any other questions, please talk to your healthcare professional.



# Menopause Basics

**Menopause** occurs after the age of 45 for most women. The Society of Obstetricians and Gynecologists of Canada defines menopause as “the point in time when a woman has had no menstrual period for 12 consecutive months.” After 12 months, the term **postmenopausal** may also be used. Approximately 60–80% of women will experience ‘vasomotor symptoms’ of menopause, which may include hot flashes, flushing and night sweats. These may resolve on their own but, in some women, treatment with medication can help manage these symptoms.



**Vasomotor symptoms of menopause may include hot flashes, flushing, and night sweats.**

## What is Hormone Replacement Therapy (HRT)?

Hormone replacement therapy, or HRT, is used to treat some symptoms that occur when a woman's estrogen level drops after menopause such as hot flashes, flushing, and night sweats. There are different types of HRT, such as medications that contain estrogen alone, a combination of estrogen and progesterone (called combined HRT) or tibolone (the active ingredient in Tibella®).

## What is Tibella®?

Tibella® contains the molecule named tibolone which is a hormone replacement therapy (HRT) used to treat some symptoms that occur when the level of estrogen produced by a woman's body drops after menopause. These symptoms can include hot flashes, flushing and night sweats.



## How does Tibella® work?

Tibella® is different from other HRTs, as it does not contain actual hormones. Instead, your body breaks down tibolone to make three substances that act like *estrogen*, *progesterone* and *testosterone*. These substances act on different tissues in the body to help treat symptoms of menopause.



## What is Tibella® used for?

Tibella® is used to treat some of the symptoms that occur when the level of estrogen produced by a woman's body drops after menopause. Tibella® should be used for short-term treatment in postmenopausal women. Only women with an intact uterus should take Tibella®. Tibella® is not for use to prevent pregnancy.

Talk to your healthcare professional about your specific condition and ask if there is any new information about Tibella®.

## What is in Tibella®?

Tibella® contains the molecule known as tibolone, which is the active (medicinal) ingredient. The non-medicinal ingredients are: ascorbyl palmitate, lactose monohydrate, magnesium stearate, mannitol, and potato starch.



## Who should not take <sup>c</sup>Tibella®?

### You should not use Tibella® if you:

- are allergic to tibolone, any of its ingredients, or components in the container;
- have, or have had, liver disease with abnormal liver function tests;
- have, or may have, estrogen-sensitive cancer, such as endometrial cancer;
- have endometrial hyperplasia (untreated overgrowth of the uterus lining);
- have, may have, or have had, breast cancer;
- have unexplained vaginal bleeding;
- are pregnant, think you may be pregnant, or are breastfeeding;
- have, or have had, cardiovascular conditions including: heart attack, stroke, angina, coronary heart disease, transient ischemic attack, deep vein thrombosis, pulmonary embolism, or thrombophlebitis;
- have a blood clotting disorder, such as protein C, protein S, or anti-thrombin deficiency;
- have vision problems caused by decreased blood flow to the eye;
- have been diagnosed with porphyria.



**You must always discuss any conditions or concerns with your healthcare professional before you take Tibella® to ensure that Tibella® is appropriate for you.**

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## Are there any precautions I should know about?

The Women's Health Initiative (WHI) trial studied the benefits and risks of HRT therapy in postmenopausal women. In women taking combined estrogen and progestin (combined HRT), the trial found an increased risk of heart attack, stroke, breast cancer, as well as increased blood clots in the lungs and large veins.

Estrogens with or without progestin should be used at **the lowest effective dose** and for the **shortest period of time** possible.

Tibella® may increase your chance of having a stroke, breast cancer, or cancer of the lining of the uterus. Talk to your healthcare professional about your medical history, and get regular check-ups while you are taking Tibella®.

## What should I do before I start Tibella®?

Before you start taking Tibella®, you should see your healthcare professional, who may ask details about your past and present health, as well as your family history, to make sure Tibella® is appropriate for you. Your healthcare professional will also conduct a complete physical examination, including blood pressure, Pap smear, blood tests, breast exam, and mammogram.

After you start your Tibella® treatment, you should see your physician again in 3-6 months, and at least once a year. These check-ups will ensure you get the maximum benefit from Tibella® treatment and identify any potential side effects.



## How do I take the Tibella® tablet?

Tibella® is a tablet that is taken once a day, at the same time every day. Swallow the tablet whole with water or another drink. Do not break or chew the tablet. Tibella® may be taken with or without food.



## When to start Tibella®

You may start taking Tibella® right away:

- If you have had your ovaries surgically removed, or
- It has been at least 12 months since your last period, or
- You are being treated with medicines for endometriosis known as gonadotrophin releasing hormone (GnRH) analogues

If you are switching from another type of HRT, your healthcare professional will tell you when to start taking Tibella®.

**Tibella**®

## What if I forget to take my tablet?

If you forget to take a tablet, take it as soon as you remember. But, if it is almost time for your next dose, skip the missed tablet and continue with your next scheduled tablet. Do not take two tablets at the same time.

## Overdose

If you think you have taken too much Tibella®, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

## Can I take ‘Tibella® with other medications?

You should discuss all the medications you take, including ‘natural’ or ‘herbal’ remedies, with your healthcare professional. Tibella® may interact with certain substances, including medicines that prevent blood clots (warfarin, anticoagulants) and herbal products (St. John’s Wort). Other medications that may interact with Tibella® are medications used to treat epilepsy (phenobarbitone, phenytoin and carbamazepine), tuberculosis (rifampicin), diabetes, and high blood pressure, as well as a medication called midazolam.

## Are there any possible effects I should know about?

Tibella® has benefits and risks. Consider them when deciding to start taking Tibella® or to carry on taking it. You should talk with your healthcare professional regularly about whether you still need treatment with HRT.

Tibella® may produce some unwanted side effects. If you experience any side effects not listed here, contact your healthcare professional.

You may experience some irregular vaginal bleeding, just drops of blood or spotting, in the first 3–6 months of Tibella® treatment. If this bleeding continues for more than 6 months, you should see your physician as soon as possible.

Some possible side effects reported by some women include:

**irregular vaginal bleeding** in the first 3-6 months of taking Tibella®

fatigue • abdominal pain • nausea/vomiting  
appetite changes • weight changes • breast pain/discomfort  
vaginal infections or symptoms • changes in hair growth/loss  
skin rashes • change in skin colour • swelling of extremities  
dizziness/headache, memory loss • mood changes  
vision changes • joint/muscle pain • heart fluttering/pounding  
change in sex drive • painful intercourse • difficulty urinating

**Serious side effects have occurred.**

**Uncommon and/or rare side effects may include:**

breast abnormalities • stroke • pulmonary embolism  
deep vein thrombosis • thrombophlebitis • endometrial hyperplasia  
severe vaginal bleeding • coronary artery disease  
ovarian/endometrial cancer • high blood pressure  
liver disorders • neuritis • cystitis • erythema multiforme  
erythema nodosum • high blood sugar



**If you are concerned about any serious symptoms, stop taking Tibella® and consult your healthcare professional immediately.**

## How do I store my Tibella®?

Your Tibella® tablets should be stored in their package – the blister cards in the outer carton – at room temperature (15° C–30° C), protected from light and moisture. Do not use Tibella® after the expiry date on the packaging.

Like all medications, keep Tibella® out of the reach and sight of children.

**Tibella®**

## Where can I get more information?

Your healthcare professional is the best source of information about your specific condition and treatment. However, for general information about menopause, you may find the following resources helpful.

- **The Society of Obstetricians and Gynaecologists of Canada**  
[www.menopauseandu.ca](http://www.menopauseandu.ca)
- **Canadian Menopause Society**  
[www.sigmamenopause.com](http://www.sigmamenopause.com)



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