What is Livial?
LIVIAL (tibolone 2.5 mg) is a hormone replacement therapy (HRT) designed to relieve menopausal symptoms in post-menopausal women. If you are at an increased risk of fractures due to osteoporosis but are unable to take other hormones, or if other therapies prove to be ineffective, LIVIAL may also be used for this purpose.

LIVIAL contains tibolone, a synthetic hormone derived from the Mexican yam.

LIVIAL does not contain oestrogen, but mimics the action of the hormones produced by the ovaries prior to menopause.

How does Livial work?
LIVIAL has some similar effects to oestrogen in the body, however it works in a different way because it is not oestrogen.

LIVIAL is converted or broken down in the body into three other substances, which act like oestrogen, progesterone or testosterone, depending on what part of the body the substance is in.

LIVIAL acts like oestrogen in the brain, bone and in vaginal tissue.

LIVIAL also acts like progesterone in the uterus to prevent overgrowth of the lining that may result in bleeding. LIVIAL also has testosterone-like activity that appears to play a role in enhancing a woman’s mood and libido.

How does Livial differ from oestrogen?
LIVIAL is used for short-term relief of menopausal symptoms in the same way as oestrogen is used.

LIVIAL does not act like oestrogen on the lining of the uterus. As a result some women may experience bleeding and spotting initially. For most women this subsides after the first few months of treatment.

In addition, as LIVIAL does not cause significant increase in the density of breast tissue, it makes mammograms easier to read.

LIVIAL has also been shown to have a beneficial effect on mood and sexual desire.

How do I take Livial?
LIVIAL is a small white tablet that is taken by mouth at the same time each day. It can be taken with or without food. Do not leave a break between strips or packs of LIVIAL.

When can I start taking Livial?
LIVIAL is intended for post-menopausal women. If it has been less than one year since your last period, your doctor will be able to advise you as to whether LIVIAL is suitable for you. When you can start taking LIVIAL depends on whether or not you are currently taking HRT or have had a hysterectomy:

• If you are not currently taking HRT, or you have had a hysterectomy, you can start any time.
• If you take HRT that contains the same amount of oestrogen and progestogen every day of the month, you can start LIVIAL the day after you stop your current HRT.

What if I forget to take a dose?
If you forget to take a tablet, take it as soon as you remember, unless you are more than 12 hours late. If you are more than 12 hours late, skip the dose you missed and take your next dose when you are meant to. Please read the Consumer Medicine Information (CMI) or consult with your doctor or pharmacist.

Do not take a double dose to make up for the forgotten dose.
Will LIVIAL interfere with any other medications I may be taking?

Some medicines may interfere with the effects of LIVIAL. This applies to the following medicines:

- medications used to thin the blood after a blood clot, e.g. warfarin
- medicines for epilepsy, e.g. phenytoin and carbamazepine
- medicines for tuberculosis, e.g. rifampicin.
- herbal remedies that contain St John’s Wort.

It is important to tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Can I use LIVIAL if I have had a hysterectomy?

Yes. For women who do not have a uterus, LIVIAL may still offer relief of menopausal symptoms.

What are the potential side effects of LIVIAL?

LIVIAL helps most women with menopausal symptoms, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not.

Do not be alarmed by the following list of side effects. You may not experience any of them. Side effects observed in clinical studies were: vaginal bleeding or spotting, abdominal pain, weight gain, breast pain, unnatural hair growth, vaginal symptoms (such as discharge, itching, and irritation) and acne. Other side effects that have been reported since the product was launched are: dizziness, headache, migraine, depression, rash or itching, visual disturbances, gastrointestinal upset, fluid retention, joint pain, muscle pain and changes in liver function. There have been reports of breast cancer and of an increased cell growth or cancer of the lining of the womb in women using LIVIAL.

Tell your doctor if you experience any side effects and they worry you.

The following side effects have been reported with other HRTs:

- gall bladder disease
- various skin disorders: discoloration of the skin, especially the face or neck, painful reddish skin nodules, rash with target-shaped reddening or sores.

The following diseases are reported more often in women using HRT compared to women not using HRT:

- breast cancer
- abnormal growth or cancer of the lining of the womb
- ovarian cancer
- blood clots in the veins of the legs or lungs
- heart disease
- stroke
- probable memory loss if HRT is started over the age of 65.

Do not be alarmed by these side effects. Your doctor will be watching for them. It is a good idea to discuss with your doctor or pharmacist, as soon as possible, any side effects, including prolonged bleeding or spotting, that continue or become troublesome.

Will I put on weight if I take LIVIAL?

It depends. As women get older, their metabolic rate decreases. This means that it is harder to burn the calories that are consumed.

Some women may find that their weight increases with LIVIAL treatment. A healthy diet and lifestyle, including regular exercise, may lower your risk for many health problems associated with ageing.
Who should not take LIVIAL?

You should not take LIVIAL if you:

- are pregnant or breastfeeding
- currently have or have had breast cancer, or if you are suspected of having it
- have cancer which is sensitive to oestrogens, such as cancer of the womb lining (endometrium), or if you are suspected of having it
- have any unexplained vaginal bleeding
- have excessive thickening of the womb lining (endometrial hyperplasia) that is not being treated
- have a blood clotting disorder
- have or have ever had a blood clot in a vein (thrombosis), such as in the legs or the lungs
- have or recently have had a disease caused by blood clots in the arteries, such as a heart attack, stroke or angina
- currently have or have had liver disease and your liver function tests have not returned to normal
- have a rare blood problem called porphyria which is passed down in families (inherited)
- are allergic (hypersensitive) to tibolone, or any of the other ingredients of LIVIAL.

If any of the above conditions appear for the first time while taking LIVIAL, stop taking it at once and consult your doctor immediately.

Summary

LIVIAL is effective at relieving hot flushes, night sweats and vaginal dryness associated with loss of natural oestrogen. Improvement of symptoms generally occurs within a few weeks and maximum effect is usually seen when therapy is continued for at least 3 months. HRT should be prescribed at the lowest effective dose, for the shortest duration necessary. Your doctor can advise you how long you may need to take LIVIAL. Some women using LIVIAL experience minimal breast pain and tenderness. LIVIAL does not significantly increase breast density. This means that when you have a mammogram, it may be easier for the doctor to see changes in the breast. Be sure to regularly check your breasts for any changes such as dimpling of the skin, changes in the nipple, or any lumps you can see or feel. In women taking LIVIAL, any bleeding or spotting usually subsides after the first few months of treatment. LIVIAL does not act as an oestrogen on the lining of the uterus. LIVIAL improves thinning of the vaginal wall and also relieves vaginal-related symptoms such as discomfort, dryness and pain during intercourse. For further information please discuss with your doctor or pharmacist. You can also read the Consumer Medicine Information for LIVIAL which is available from your doctor or pharmacist. There is also a copy inserted in every prescribed LIVIAL pack.

This information leaflet is to be given by healthcare professionals to patients who have been prescribed Livial tablets. If you have any questions about why you have been prescribed Livial or concerns about your medication, ask your doctor or pharmacist and refer to the Consumer Medicines Information leaflet available from: www.msdinfo.com.au/livialcmi

References:
1. Consumer Medicine Information for LIVIAL.