

LIVIAL TABLET®

Tibolone (2.5 mg)

What is in this leaflet:

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What *LIVIAL* is used for Relief of symptoms occurring after menopause

During the menopause, the amount of estrogen produced by a woman's body drops. This can cause symptoms such as hot face, neck and chest ("hot flushes"). *LIVIAL* alleviates these symptoms after menopause. You will only be prescribed *LIVIAL* if your symptoms seriously hinder your daily life.

Prevention of osteoporosis

To prevent osteoporosis (fragile bones) in women who are at high risk of fractures after menopause. You can take *LIVIAL* if other medicines are not suitable for you.

How *LIVIAL* works

LIVIAL is a Hormone Replacement Therapy (HRT). *LIVIAL* contains tibolone, a substance that has favorable effects on different tissues in the body, such as brain, vagina and bone. *LIVIAL* is used in postmenopausal women with at least 12 months since their last natural period. This results in the relief of climacteric symptoms such as hot flushes and night sweats, a beneficial effect on the lining of the vagina and a favorable effect on mood and sexual desire. *LIVIAL* can also stop the process of bone loss that occurs after the menopause in your spine, hip and wrists. Unlike some hormone replacement therapies, *LIVIAL* does not stimulate the lining of the womb. Treatment with *LIVIAL* therefore does not lead to monthly vaginal bleeding.

Before you take *LIVIAL*

- When you must not take it

Do not take *LIVIAL*

If any of the following applies to you. If you are not sure about any of the points

below, **talk to your doctor** before taking *LIVIAL*.

Do not take *LIVIAL*

- If you have or have ever had **breast cancer**, or if you are suspected of having it.
- If you have **cancer which is sensitive to estrogens**, such as cancer of the womb lining, or if you are suspected of having it.
- If you have any **unexplained vaginal bleeding**.
- If you have **excessive thickening of the womb lining** that is not being treated.
- If you have or have ever had a **blood clot in a vein**, such as in the legs or the lungs.
- If you have a **blood clotting disorder** (such as protein C, protein S, or antithrombin deficiency).
- If you have or recently have had a disease caused by blood clots in the arteries, such as a **heart attack, stroke or angina**.
- If you have or have ever had a **liver disease** and your liver function tests have not returned to normal.
- If you have a rare blood problem called "porphyria" which is passed down in families (inherited).
- If you are **allergic** (hypersensitive) to **tibolone** or any of the other ingredients of *LIVIAL* (listed in "**Product description, Ingredients**").
- If you are **pregnant** or think you may be pregnant.
- If you are **breastfeeding**.

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

- Before you start to take *LIVIAL*

Medical history and regular check-ups

The use of HRT or *LIVIAL* carries risks which need to be considered when deciding whether to start taking it, or whether to carry on taking it.

The experience in treating women with a premature menopause (due to ovarian failure or surgery) is limited. If you have a premature menopause the risks of using HRT or *LIVIAL* may be different. Please talk to your doctor.

Before you start (or restart) HRT or *LIVIAL*, your doctor will ask about your own and your family's medical history. Your doctor may decide to perform a physical examination. This may include an examination of your breasts and/or an internal examination, if necessary.

Once you have started on *LIVIAL* you should see your doctor for regular check-ups. At these check-ups, discuss with your doctor the benefits and risks of continuing with *LIVIAL*.

Go for regular breast screening, as recommended by your doctor.

When to take special care with *LIVIAL*

Tell your doctor if you have ever had any of the following problems, before you start the treatment, as these may return or become worse during treatment with *LIVIAL*. If so, you should see your doctor more often for check-ups:

- fibroids inside your womb
- growth of the womb lining outside your womb or a history of excessive thickening of the womb lining
- increased risk of developing blood clots (see "Blood clots in a vein (thrombosis)")
- increased risk of getting an oestrogen-sensitive cancer (such as having family history of breast cancer)
- high blood pressure
- a liver disorder, such as a benign liver tumour
- diabetes
- gallstones
- migraine or severe headaches
- a disease of the immune system that affects many organs of the body (systemic lupus erythematosus, SLE)
- epilepsy
- asthma
- deafness or hearing loss due to bone growth in the ear
- a very high level of fat in your blood (triglycerides)
- fluid retention due to heart or kidney problems

Stop taking *LIVIAL* and see a doctor immediately

If you notice any of the following when taking HRT or *LIVIAL*:

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- any of the conditions mentioned in the "Do not take *LIVIAL*" section
- yellowing of your skin or the whites of your eyes (jaundice). These may be signs of a liver disease
- a large rise in your blood pressure (symptoms may be headache, tiredness, dizziness)
- migraine-like headaches which happen for the first time
- if you become pregnant
- if you notice signs of a blood clot, such as:
 - painful swelling and redness of the legs
 - sudden chest pain
 - difficulty in breathing

For more information, see "Blood clots in a vein (thrombosis)".

Note: *LIVIAL* is not a contraceptive. If it is less than 12 months since your last menstrual period or you are able to conceive, you may still need to use additional contraception to prevent pregnancy. Speak to your doctor for advice

HRT and cancer

There have been reports and studies of an increased cell growth or cancer of the lining of the womb in women using *LIVIAL*. The risk of cancer of the lining of the womb increases with the duration of use.

Irregular bleeding

You may have irregular bleeding or drops of blood (spotting) during the first months of taking *LIVIAL*.

However, if the irregular bleeding:

- carries on for more than the first 6 months
- starts after you have been taking *LIVIAL* for more than 6 months
- carries on after you have stopped taking *LIVIAL*

see your doctor as soon as possible.

Breast cancer

Evidence suggests that taking combined estrogen-progestogen and possibly also estrogen-only HRT increases the risk of breast cancer. The extra risk depends on how long you take HRT. The additional risk becomes clear within a few years. However, it returns to normal within a few years (at most 5) after stopping treatment.

Compare

Women taking *LIVIAL* have a lower risk than women using combined HRT and a comparable risk with estrogen-only HRT.

Regularly check your breasts. See your doctor if you notice any changes such as:

- dimpling or sinking of the skin
- changes in the nipple
- any lumps you can see or feel

Ovarian cancer

Ovarian cancer is rare. A slightly increased risk of ovarian cancer has been reported in women taking HRT for at least 5 to 10 years.

Compare

With use of *LIVIAL*, the increased risk of ovarian cancer is similar to other types of HRT.

Effect of HRT on heart and circulation

Blood clots in a vein (thrombosis)

The risk of **blood clots in the veins** is about 1.3 to 3-times higher in HRT users than in non-users, especially during the first year of taking it.

Blood clots can be serious, and if one travels to the lungs, it can cause chest pain, breathlessness, fainting or even death.

You are more likely to get a blood clot in your veins as you get older and if any of the following applies to you. Inform your doctor if any of these situations apply to you:

- you are pregnant or recently had a baby
- you use estrogens
- you are unable to walk for a long time because of major surgery, injury or illness (see "While you are taking *LIVIAL*, If you need to have surgery")
- you are seriously overweight (BMI >30 kg/m²)
- you take any medicine used to prevent blood clots
- if any of your close relatives has ever had a blood clot in the leg, lung or another organ

- you have systemic lupus erythematosus (SLE)
- you have cancer.

For signs of a blood clot, see "Stop taking *LIVIAL* and see a doctor immediately".

Compare

Looking at women in their 50s who are not taking HRT, on average, over a 5-year period, 4 to 7 in 1000 would be expected to get a blood clot in a vein.

With use of *LIVIAL*, the increased risk of getting a blood clot in a vein is lower than with other types of HRT.

Heart disease (heart attack)

There is no evidence that HRT or *LIVIAL* will prevent a heart attack.

Women over the age of 60 who use estrogen-progestogen HRT are slightly more likely to develop heart disease than those not taking any HRT. The risk of heart disease strongly depends on age and will rise with more advanced age.

There is no evidence to suggest that the risk of heart attack with *LIVIAL* is different to the risk of other HRT.

Stroke

Recent research suggests that HRT and *LIVIAL* increases the risk of having a stroke. This increased risk has mainly been observed in elderly postmenopausal women above 60 years of age.

Compare

Looking at women in their 50s who are not taking *LIVIAL* — on average, over a 5-year period, 3 in 1000 would be expected to have a stroke. For women in their 50s who are taking *LIVIAL*, the figure would be 7 in 1000 (i.e. an extra 4 cases).

Looking at women in their 60s who are not taking *LIVIAL* — on average, over a 5-year period, 11 in 1000 would be expected to have a stroke. For women in their 60s who are taking *LIVIAL*, the figure would be 24 in 1000 (i.e. an extra 13 cases).

Other conditions

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HRT will not prevent memory loss. There is some evidence of a higher risk of memory loss in women who start using HRT after the age of 65. Speak to your doctor for advice.

Use in pregnancy and breast-feeding

LIVIAL is for use in postmenopausal women only. If you become pregnant, stop taking *LIVIAL* and contact your doctor.

- Taking other medicines

Some medicines may interfere with the effect of *LIVIAL*. This might lead to irregular bleeding. This applies to the following medicines:

- Medicines against **blood clotting** (such as warfarin)
- Medicines for **epilepsy** (such as, carbamazepine)
- Medicines for **tuberculosis (bacterial infection that mainly affects the lungs)** (such as rifampicin)
- Herbal remedies containing **St John's Wort** (*Hypericum perforatum*).

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines including medicines obtained without a prescription, herbal medicines or other natural products.

Taking *LIVIAL* with food and drink.

You can eat and drink normally while you are taking *LIVIAL*.

How to take *LIVIAL*

- How much to take

Follow all directions given to you by your doctor carefully. If you do not understand the instructions in this leaflet, ask your doctor for help. *LIVIAL* is for oral use. Take one tablet each day. Swallow it with some water or other drink. Take the tablet at the same time each day.

- When to take it

The strips with *LIVIAL* are marked with the days of the week. Start by taking the tablet marked with that day. For example, if it is a Monday, take a tablet marked Monday on the upper row of the strip. Follow the days of the week until the strip is empty. Start the next strip the next day. Do not leave a break between strips or packs.

LIVIAL should not be taken until twelve months after your last natural menstrual bleed. If *LIVIAL* is taken sooner than this, the chance of irregular vaginal bleeding may be increased.

- How long to use it

Continue using *LIVIAL* for as long as your doctor recommends.

Your doctor will aim to prescribe the lowest dose to treat your symptoms for as short as necessary. Speak to your doctor if you think this dose is too strong or not strong enough.

- If you forget to use it

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, just skip it and the next dose should be taken at the normal time. Missing a dose may increase the likelihood of breakthrough bleeding and spotting.

Do not take a double dose to make up for forgotten individual doses.

- If you use too much (overdose)

If you may have taken more *LIVIAL* than you should, talk to a doctor or pharmacist immediately.

If anybody takes too many tablets, there is no need for great concern. However, you should talk to your doctor straight away. Signs of an overdose may include feeling sick, being sick or vaginal bleeding.

While you are taking *LIVIAL*

- Things you must do

Take your medicine exactly as your doctor has told you

Tell all the doctors, dentists and pharmacists treating you that you are taking *LIVIAL*.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give *LIVIAL* to anyone else, even if they have the same symptoms or condition as you.

If you need to have surgery

If you are going to have surgery, tell the surgeon that you are taking *LIVIAL*.

You may need to stop taking *LIVIAL* about 4 to 6 weeks before the operation to reduce the risk of a blood clot (see "Blood clots in a vein"). Ask your doctor when you can start taking *LIVIAL* again.

- Things you must be careful of

Driving and using machines

As far as is known, *LIVIAL* has no effect on alertness and concentration.

Side effects

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 (endometrial hyperplasia or cancer)
- ovarian cancer
- blood clots in the veins of the legs or lungs (venous thromboembolism)
- heart disease
- stroke
- probable memory loss if HRT is started over the age of 65

Like all medicines, *LIVIAL* may have side effects. Most of these side effects are mild.

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 irritation

An uncommon side effect (occurring in 0.1-1% of the women using *LIVIAL*) was acne.

Other side effects observed with *LIVIAL* in market use were:

- Dizziness, headache, migraine, depression
- Rash or itching
- Visual disturbances
- Gastro-intestinal upset
- Fluid retention
- Joint pain, muscle pain
- Changes in liver function

Tell your doctor if any of the above mentioned side effects become troublesome or continue.

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The following side effects have been reported with other HRTs:

- gall bladder disease
- various skin disorders:
 - discoloration of the skin especially of the face or neck known as “pregnancy patches”(chloasma)
 - painful reddish skin nodules (erythema nodosum)
 - rash with target-shaped reddening or sores (erythema multiforme)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of LIVIAL

- *Storage*

Keep *LIVIAL* out of reach and sight of children.

Keep your *LIVIAL* tablets in the original package and in the outer carton below 25°C. Check if there are special storage conditions given on the box.

Do not use *LIVIAL* after the expiry date stated on the carton.

How long should I keep my medicine?

Do not use this medicine after the month and year shown by the four numbers following EX (or EXP) on the container. The first two numbers indicate the month; the last two numbers indicate the year.

- *Disposal*

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product description

- *What it looks like*

LIVIAL 2.5 mg tablets are white round and flat tablets with beveled edges, coded “MK” above “2” on one side and “Organon” on the other side. They come in cardboard boxes containing one or three packs of 28 tablets.

- *Ingredients*

- Active ingredient: Tibolone 2.5 mg

- Inactive ingredients: Potato Starch, Lactose, Ascorbyl Palmitate, and Magnesium Stearate.

LIVIAL tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

- *MAL number*

MAL19913394AZ

Manufacturer

N.V. ORGANON
KLOOSTERSTRAAT 6,5349 AB
OSS, NETHERLANDS

Product Registration Holder

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