

LIVIAL (See SmPC before Prescribing)

Presentation: Calendar pack of 28 Livial tablets, each containing 2.5mg of tibolone. **Uses:** Treatment of oestrogen deficiency symptoms in postmenopausal women. Second line therapy for prevention of osteoporosis in postmenopausal women at high risk of future fractures who are intolerant of, or contraindicated for, other medicinal products approved for the prevention of osteoporosis. **Dosage and administration:** 2.5mg Livial orally once daily. HRT should only be continued as long as the benefit in alleviation of severe symptoms outweighs the risk. Not to be taken by women experiencing a natural menopause until 12 months after their last natural menstrual bleed. Changing from another HRT preparation; see SmPC for full details. **Contraindications:** Pregnancy. Lactation. Known, past or suspected breast cancer. Known or suspected oestrogen-dependent malignant tumours. Untreated endometrial hyperplasia. Undiagnosed vaginal bleeding. Previous or current VTE. Active or recent arterial thromboembolic disease. Acute liver disease or a history of liver disease as long as liver function tests have failed to return to normal. Hypersensitivity to any constituents of Livial. Porphyria. **Precautions and warnings:** A full medical history should be taken before treatment. An appraisal of the risks and benefits should be undertaken at least annually. Patients with some medical conditions will need close supervision particularly when the condition is active, or has occurred previously and/or was aggravated during pregnancy or previous hormone treatment - see SmPC for full details of these conditions, which may recur or be aggravated during treatment with Livial. Discontinue treatment if: a contraindication occurs, jaundice or a deterioration in liver function occurs, there is a significant increase in blood pressure or a new onset of migraine. Break-through bleeding or spotting may occur in the first months of treatment. If bleeding continues during therapy or after discontinuation it should be investigated. For full details on the warnings associated with HRT and endometrial safety, breast cancer, VTE, coronary arterial disease, stroke and ovarian cancer refer to SmPC. Livial tablets contain lactose (see SmPC for details). **Interactions:** No examples of interactions between Livial and other medicines have been reported in clinical practice. The following potential interactions could theoretically occur: enzyme inducing compounds e.g. barbiturates, carbamazepine, hydantoin and rifampicin may enhance the metabolism of tibolone and decrease its therapeutic effect. Livial may increase blood fibrinolytic activity and may enhance the effect of anticoagulants, such as warfarin. The use of Livial with warfarin should be monitored, especially when starting or stopping concurrent Livial treatment, and the warfarin dose should be appropriately adjusted. **Adverse reactions:** The following are the most commonly reported in clinical trials: abdominal pain, weight increase, vaginal bleeding or spotting, leukorrhea, breast pain, genital pruritus, genital moniliasis, vaginitis, hypertrichosis. Other events reported occasionally include: dizziness, rash, seborrhoeic dermatosis, headache, migraine, visual disturbances, GI upset, depression, oedema, effects on the musculoskeletal system and changes in liver function parameters - see SmPC for full details.

UK Legal category: POM.

Product licence number PL 0065/0086. **Package quantities:** 1 x 28 tablets, 3 x 28 tablets

Basic NHS Cost: 1 x 28 tablets £10.77, 3 x 28 tablets £32.29

Product licence holder: Organon Laboratories Limited, Cambridge Science Park, Milton Road, Cambridge, CB4 0FL

Further information is available from: Organon Laboratories Limited, Cambridge Science Park, Milton Road, Cambridge, CB4 0FL Telephone: 01223 432700.

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Help safeguard public health and support medicines yellow card reporting.

UK – see www.yellowcard.gov.uk

Alternatively, adverse events can be reported to Organon Laboratories by calling 01223 432740.