Lobion-HRT
(Tibolone)

لوبیون-ایچ آر ٹی
(ٹیبولون)

2.5 mg Tablets

2.5 ملی گرام گولیاں

COMPOSITION
Each tablet contains:
Tibolone (B.P.) ..... 2.5 mg
Product Complies B.P. Specs.

PHARMACODYNAMIC PROPERTIES
After oral administration tibolone is rapidly metabolized into three compounds which contribute to the pharmacological effects of Tibolone (***Lobion-HRT***). Two of these metabolites have predominantly estrogenic activity.

Tibolone (***Lobion-HRT***) has an estrogen-like effect on hot flushes and other climacteric complaints. In addition, estrogen-like effects are exerted on the vagina and bone. Due to its progestagenic effects Tibolone (***Lobion-HRT***) does not stimulate the endometrium. Therefore, if bleeding occurs, this usually results from an atrophic endometriurn. Finally, Tibolone (***Lobion-HRT***) has effects on certain metabolic and haematological parameters such as a decrease in plasma high density lipoprotein cholesterol, triglycerides, lipoprotein(a), and an increase in blood fibrinolytic activity.

PHARMACOKINETIC PROPERTIES
After oral administration Tibolone (***Lobion-HRT***) is rapidly and extensively absorbed. Due to rapid metabolism the plasma levels of tibolone are very low, Pharmacokinetic data indicate linear kinetics. Peak plasma levels are reached after 1-4 hours and accumulation does not occur. Excretion of Tibolone (***Lobion-HRT***) is mainly in the form of polar and very polar metabolites. A small amount of the administered compound is excreted in the urine, but most is eliminated via the bile and the faeces.

INDICATIONS
- Complaints resulting from the natural or surgical menopause.
- Prevention of postmenopausal osteoporosis.

DOSAGE AND ADMINISTRATION
The dosage is one tablet per day. The tablets should be swallowed with some water or other drink, preferably at the same time each day. Improvement of symptoms generally occurs within a few weeks, but optimal results are obtained when therapy is continued for at least 3 months.

At the recommended dosage, Tibolone (***Lobion-HRT***) may be used without interruption for longer periods. A missed dose should be taken as soon as remembered unless it is more than 12 hours overdue. In the later case, the missed dose should be skipped and the next dose should be taken at the normal time.

CONTRAINDICATION
- Pregnancy
- Known or suspected hormone-dependent tumours
- Cardiovascular or cerebrovascular disorders, e.g. thrombophlebitis thrombo embolic processes or a history of these conditions.
- Undiagnosed vaginal bleeding.
- Severe liver disorders.

WARNINGS AND PRECAUTION
- Tibolone (***Lobion-HRT***) is not intended for contraceptive use.
- Risk-benefit should be considered when any of the following medical conditions exist
  - Liver disease or a history of this condition
  - Hypercholesterolaemia
- The use of Tibolone (***Lobion-HRT***) should be avoided until 12 months after the last natural menstrual bleed. If Tibolone (***Lobion-HRT***) is taken sooner than this, the frequency of irregular bleeding may be increased.
- If changing from another hormone replacement preparation, induction of a withdrawal bleed with a progestagen is advisable before starting Tibolone (***Lobion-HRT***).
- The occurrence of vaginal bleeding or spotting soon after starting treatment with Tibolone (***Lobion-HRT***) may be due to the residual effects of endogenous or exogenous estrogens. Bleeding commencing after three months of treatment, or recurrent or persistent bleeding should be investigated.
- As for all steroids with hormonal activity, yearly medical examination is advisable.
- Treatment should be discontinued if signs of thrombo-embolic processes occur, if results of liver function tests become abnormal, or if cholestatic jaundice appears.

INTERACTIONS
No examples of interactions between Tibolone (***Lobion-HRT***) and other medicines have been reported in Clinical practice. However, the following potential interactions should be considered on a theoretical basis.
- Enzyme-inducing compounds such as barbiturates, carbamazepine hydantoins, and rifampicin may enhance the metabolism of tibolone and thus decrease its therapeutic effect.
- Since tibolone may increase blood fibrinolytc activity (lower fibrinogen levels higher AT III, plasminogen, and fibrinolytic activity values), it may enhance the effect of anticoagulants

ADVERSE REACTIONS
Occasionally, vaginal bleeding or spotting may occur, mainly during the first months of treatment. Other adverse events that have been occasionaly observed include: headache and migraine odema dizziness, pruritus, increase in body weight, nausea, abdominal pain, rash, and depression.

PREGNANCY AND LACTATION
Tibolone (***Lobion-HRT***) Is contraindicated in pregnant and lactating women.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES
As far as is known Tibolone (***Lobion-HRT***) has no effect on alertness and concentration.

OVERDOSE
The acute toxicity of tibolone in animals is very low. Therefore, toxic symptoms are not expected to occur if several tablets are taken simultaneously. In case of acute overdose, nausea, vomiting, and withdrawal bleeding in females may develop. No specific antidote is known. Symptomatic treatment can be given if necessary.

PRESENTATION
Pack of 30 tablets in blister pack.

STORAGE
Store below 30°C in a dry place, protect from light.
To be dispensed on the prescription of a registered medical practitioner only.
Keep out of the reach of children.

ہدایات:

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر خشک جگہ پر رکھیں،

روشنی سے بچائیں۔ صرف رجسٹرڈ ڈاکٹر کے نسخے پر فروخت کریں۔

بچوں کی پہنچ سے دور رکھیں۔

Note: Product contains lactose. **نوٹ: پروڈکٹ میں لیکٹوز شامل ہے۔**

Manufactured by:
Platinum
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