CONTRACEPTIVES
Urufarma

Paraclim

Tibolone 2.5 mg

Formula:
Each coated tablet contains tibolone 2.5 mg and excipients (q.s.)

Therapeutic effect:
Tibolone is a synthetic steroid with oestrogenic, androgenic, and progestogen activities. It relieves usual symptoms of climacteric syndrome, such as hot flushes, sweating, vaginal dryness, etc. Tibolone exerts its oestrogenic effects on the vagina and bones. Due to its progestogen effect, tibolone does not stimulate the endometrium. Possible haemorrhages come from an atrophic endometrium. Tibolone acts on a number of metabolic and haematologic parameters, causing a decrease in the plasma levels of HDL-cholesterol, triglycerides, and alfa-lipoprotein, and increasing fibrinolytic activity. On the other hand, it appears to have beneficial effects on osteoporosis after menopause.

Indications:
This medicine is used to treat the climacteric syndrome after one year of natural menopause or immediately after surgical menopause.

Pharmacological characteristics:
Oral tibolone is rapidly and fully absorbed. It can be found in plasma within 30 minutes of dosing, with peak concentrations after 1.5 to 4 hours.
The plasma protein binding is about 98%.
It is metabolised in the liver and intestines.
It is mainly excreted in faeces and no enterohepatic circulation has been found.

Posology and method of administration:
The recommended initial dose for treatment of climacteric symptoms is 1 daily tablet of 2.5 mg. Generally, symptoms improve within a few weeks. Best results are found when the treatment lasts at least three consecutive months. You can take the tablets with water or any other fluid, at the same time each day, if possible. Dose adjustments are not required in elderly patients.
If you miss a dose, take it as soon as possible unless 12 hours have passed, in which case you should skip the dose entirely and resume the usual dosage regime.

Contraindications:
Pregnancy and breastfeeding.
Diagnosed or suspected hormone-dependent tumours. Cardiovascular and cerebrovascular diseases, such as thromboembolism and thrombophlebitis
Genital haemorrhage of unknown origin. Severe liver function abnormalities. Endometriosis
Tibolone should not be used in women with known or suspected breast cancer, or those with a history of breast cancer.

Precautions and warnings:
Taking of **Paraclim** within 12 months after the last menstrual bleeding may induce irregular vaginal haemorrhages, and thus should be used after that.
Doses over the recommended dose could induce bleeding as well.
If you have been taking another hormone replacement therapy before treatment with **Paraclim**, haemorrhage should be induced by deprivation, by means of a progestogen.
If signs of thrombophlebitis, thromboembolic processes, altered liver tests, jaundice, or any of the situations listed as contraindications occur, discontinue the treatment.
Special monitoring and follow-up should be done in patients with a history of renal failure, epilepsy, migraine, dyslipidaemia, diabetes, and glucose test intolerance (may need to increase the dose of insulin or oral antidiabetic).
Increased sensitivity to anticoagulants is possible.
Dizziness is common during treatment with tibolone. Use with caution when driving cars or operating machines that require focus.
This medicine contains lactose. Patients with hereditary intolerance to galactose, Lapp lactase insufficiency, or poor absorption of glucose or galactose should not take this medicine.

Interactions:
Products that elicit enzyme induction may increase the metabolism of tibolone, decreasing its activity (See *Warnings and Precautions*).
Adverse reactions:
Tibolone is well tolerated and significant differences in adverse reactions were generally not observed between tibolone and the placebo.
Increased body weight, change from atrophic to mildly proliferative endometrium, genital bleeding, nausea, dizziness, headache, gastrointestinal distress, changes in liver tests, increased hair growth, and pretibial oedema were occasionally observed.
- Increased risk of cerebrovascular accident (stroke) and other cardiovascular events in elderly women.
- Increased risk of endometrium cancer.
- Breast hypersensitivity.

Postmarketing studies have found:
- Skin rash
- Pruritus
- Seborrheic dermatitis
- Migraine
- Visual disturbances
- Depression
- Arthralgia (joint pain)
- Myalgia (muscle pain)

Overdose:
No cases of untreated overdose have been reported yet.

Presentation:
Pack containing 30 coated tablets.
Keep at room temperature (15 - 30°C). Keep protected from light.
In case of poisoning, seek medical assistance immediately.
Keep out of the reach of children.

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