Bestron™

Conjugated Estrogens 0.45 mg &
Bazedoxifene 20 mg

Presentation
Bestron™ : Each tablet contains Conjugated Estrogens USP 0.45 mg and Bazedoxifene INN 20 mg.

Description
Bestron is a combination of Conjugated Estrogens with Bazedoxifene. Conjugated Estrogens and Bazedoxifene function by binding to and activating estrogen receptors (ER) α and β. Bazedoxifene is an estrogen agonist / antagonist that acts as an agonist in some estrogen-sensitive tissues and an antagonist in others (e.g. uterus).

Indications and Usage
Bestron is indicated for treatment of moderate to severe vasomotor symptoms associated with menopause and prevention of postmenopausal osteoporosis.

Dosage and Administration
Take Bestron once daily, without regard to meals. Tablets should be swallowed whole. Women taking Bestron for prevention of postmenopausal osteoporosis should add supplemental calcium and/or vitamin-D to their diet if daily intake is inadequate.

Side effects
High blood pressure, blood clots, liver problems, thyroid problems, fluid retention, hypocalcemia, dementia, breast lumps, unusual vaginal bleeding, severe headache, muscle spasms, weakness and fatigue, nausea, diarrhea, throat pain, dizziness etc.

Contraindications
Bestron is contraindicated in women with undiagnosed abnormal uterine bleeding; known, suspected, or past history of breast cancer; known or suspected estrogen-dependent neoplasia; active deep venous thrombosis, pulmonary embolism, or history of these conditions; active arterial thromboembolic disease; hypersensitivity (for example, anaphylaxis, angioedema) to estrogens, bazedoxifene, or any ingredients; known hepatic impairment or other known thrombophilic disorders.

Precautions
Women taking Bestron should not take progestins, additional estrogens or additional estrogen agonist/antagonists. All women should receive yearly breast examinations by a healthcare provider and perform monthly breast self-examinations. In addition, mammography examinations should be scheduled based on patient age, risk factors, and prior mammogram results.

Use in Pregnancy and Lactation
Pregnancy: Pregnancy Category X. Bestron must not be used in women who are or may become pregnant.
Lactation: Bestron should not be used by lactating women. It is not known whether this drug is excreted in human milk. Estrogen administration to nursing mothers has been shown to decrease the quantity and quality of the milk.

Use in Children
Bestron is not indicated for use in children.

Overdosage
In case of overdosage, there is no specific antidote, and the treatment should be symptomatic. Symptoms of overdosage of estrogen-containing products may include nausea, vomiting, breast tenderness, dizziness, abdominal pain, fatigue; withdrawal bleeding may occur.

Warnings
Estrogen therapy should not be used for the prevention of cardiovascular disease or dementia. There is an increased risk of endometrial cancer in a woman with a uterus who uses unopposed estrogens.

Storage
Do not store above 30 °C. Keep away from light and out of the reach of children. After opening foil pouch, product must be used within 60 days.

Commercial pack
Bestron™ : Each box contains 2 Alu-PVDC blister strips of 10 tablets.

Manufactured by
Incepta Pharmaceuticals Ltd
Dhamrai Unit, Dhaka, Bangladesh
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V.N. 01