Exemis™

Exemestane BP Film Coated Tablet

DESCRIPTION

Exemis™ is a preparation of Exemestane. Exemestane is an irreversible, steroidal aromatase inactivator, structurally related to the natural substrate androstenedione. It acts as a false substrate for the aromatase enzyme, and is processed to an intermediate that binds irreversibly to the active site of the enzyme, causing its inactivation, an effect also known as "suicide inhibition." Exemestane significantly lowers circulating estrogen concentrations in postmenopausal women, but has no detectable effect on adrenal biosynthesis of corticosteroids or aldosterone. Exemestane has no effect on other enzymes involved in the steroidogenic pathway up to a concentration at least 600 times higher than that inhibiting the aromatase enzyme.

INDICATIONS

- Adjuvant treatment of postmenopausal women with estrogen-receptor positive early breast cancer who have received two to three years of Tamoxifen and are switched to Exemestane for completion of a total of five consecutive years of adjuvant hormonal therapy
- Treatment of advanced breast cancer in postmenopausal women whose disease has progressed following tamoxifen therapy

DOSAGE AND ADMINISTRATION

Recommended Dose: One 25 mg tablet once daily after a meal.

CONTRAINDICATIONS

Patients with a known hypersensitivity to the drug.

SIDE EFFECTS

- Hot flushes
- Fatigue
- Arthralgia
- Headache
- Insomnia
- Increased Sweating

PRECAUTION AND WARNING

- Reductions in bone mineral density (BMD) over time are seen with exemestane use
- Exemestane should not be co-administered with estrogen-containing agent as these could interfere with its pharmacologic action
- Exemestane is not indicated for the treatment of breast cancer in premenopausal women
- Routine assessment of 25-hydroxy vitamin D levels prior to the start of aromatase inhibitor treatment should be performed
- Embryo-Fetal Toxicity: Can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception

DRUG INTERACTION

Strong CYP 3A4 inducers: Concomitant use of strong CYP 3A4 inducers (e.g.: rifampicin, phenytoin, carbamazepine, phenobarbital) decreases exemestane exposure. For patients receiving Exemestane with strong CYP3A4 inducer, the recommended dose of Exemestane is 50 mg once daily.

USE IN PREGNANCY AND LACTATION

Based on findings in animal studies and its mechanism of action, Exemestane can cause fetal harm when administered to a pregnant woman. There is no information on the presence of exemestane in human milk, or on its effects on the breastfed infant or milk production. Exemestane is present in rat milk at concentrations similar to maternal plasma. Because of the potential for serious adverse reactions in breastfed infants from Exemestane, advise a woman not to breastfeed during treatment with Exemestane and for 1 month after the final dose.

PHARMACEUTICAL PRECAUTION

Do not store above 30 °C temperature. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Exemis™ FCT: Each Box contains 3 strips of 10 tablets each. Each film-coated tablet contains Exemestane BP 25 mg.

SK+F ONCOLOGY

Manufactured by
ESKAYEF PHARMACEUTICALS LIMITED
RUPGANJ, NARAYANGANJ, BANGLADESH
TM TRADEMARK
R/PM1877 V01