75 mm X 185 mm

Only for the use of Medical Professionals

Ovazol®

Letrozole

Description

Ovazol® is a preparation of Letrozole which is a highly specific nonsteroidal aromatase inhibitor. Growth of some breast cancers is stimulated by estrogens which are female sex hormones. In postmenopausal women estrogens are mainly derived from the action of the aromatase enzyme, which converts adrenal androgens to estrone and estradiol. **Ovazol®** inhibits the conversion of androgens to estrogens by inhibiting the aromatase enzyme. **Ovazol®** inhibits the aromatase enzyme by competitively binding to the heme of the cytochrome P450 subunit of the enzyme, resulting in a reduction of estrogen biosynthesis in all tissues.

Indications

Ovazol® is indicated for the first line treatment of advanced or metastatic breast cancer (hormone receptor positive or receptor status unknown) in postmenopausal women.

Dosage and administration

Adult: The recommended dose of **Ovazol®** is one 2.5 mg tablet administered once daily. Treatment should continue as long as tumor response is seen. The drug should be discontinued if tumor stops responding as judged by tumor progression.

Children: The safety and effectiveness in pediatric patients have not been established.

Elderly: No dosage adjustment is required for elderly patients. Patients treated with **Ovazol®** do not require glucocorticoid or mineralocorticoid replacement therapy.

Patients with Hepatic impairment: No dosage adjustment is required for patients with mild to moderate hepatic impairment. The dose of **Ovazol®** in patients with cirrhosis and severe hepatic dysfunction should be reduced by 50%. The recommended dose of **Ovazol®** for such patients is 2.5 mg administered every other day.

Patients with Renal impairment: No dosage adjustment is required for patients with renal impairment if creatinine clearance is ≥ 10 ml/min.

Use in pregnancy and lactation

Pregnancy: There are no adequate and well controlled studies of Letrozole in pregnant women and its use in these patients is not recommended.

Lactation: It is not known whether Letrozole is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Letrozole is administered to a nursing woman.

Side effects

Adverse events associated with Letrozole are generally mild to moderate and rarely severe enough to require discontinuation. Many can be attributed to either the underlying disease or the normal pharmacological consequence of estrogen deprivation (e.g., hot flashes, hair thinning). The most frequently reported adverse events are musculoskeletal pain, arthralgia, headache, fatigue, nausea, dyspnoea, peripheral edema, coughing, constipation, vomiting, chest pain, viral infection, diarrhoea, rash, abdominal pain, dyspepsia and anorexia. Dizziness, weight increase and pruritus are less commonly seen.

Contraindications

Letrozole is contraindicated in patients with known hypersensitivity to Letrozole or any of its components. It is also contraindicated in severe hepatic dysfunction.

Warnings and Precautions

Use of Letrozole may cause decrease in bone mineral density (BMD). Consideration should be given to monitoring BMD. In the adjuvant trial more hypercholesterolemia was reported in Letrozole patients than patients taking Tamoxifen. So, consideration should be given to monitoring serum cholesterol. Because fatigue, dizziness and somnolence have been reported with the use of Letrozole, caution is advised when driving or using machinery until it is known how the patient reacts to Letrozole use.

Drug interactions

Clinical interaction studies with Cimetidine and Warfarin indicated that the co-administration of Letrozole with these drugs does not result in clinically significant drug reactions. Co-administration of Letrozole and Tamoxifen 20 mg daily resulted in a reduction of Letrozole plasma levels of 38% on an average. Clinical experience in the second-line breast cancer trials indicates that the therapeutic effect of Letrozole therapy is not impaired if Letrozole is administrated immediately after Tamoxifen.

Overdosage

There is no clinical experience of overdosage. There is no specific antidote to Letrozole. Since, Letrozole is not highly protein bound, dialysis may be helpful. Emesis may be induced if the patient is alert. In general, supportive care and frequent monitoring of vital signs are also appropriate.

Pharmaceutical precautions

Store in a cool (below 25^{o}C) & dry place protected from light. Keep out of the reach of children.

Presentation

Ovazol® tablet: Each coated tablet contains Letrozole USP 2.5 mg.

Package quantities

Ovazol® tablet: Carton of 5 tablets in blister pack.

® Registered Trade Mark

Manufactured for
ACI Limited
Godnyl, Narayanganj, Bangladesh
by Nuvista Pharma Limited
Tongi, Gazipur, Bangladesh

030513