Feoza™

Fezolinetant INN 45 mg

Composition
Each film-coated tablet contains 45 mg Fezolinetant INN.

Pharmacology
Feoza™ is a neurokinin 3 (NK3) receptor antagonist that blocks neurokinin B (NKB) binding on the kisspeptin/neurokinin B/dynorphin (KNDy) neuron to modulate neuronal activity in the thermoregulatory center.

Method of Administration
For oral use only.

Indications and Usage
Feoza™ is indicated for the treatment of moderate to severe vasomotor symptoms due to menopause.

Dosage and Administration
Take **Feoza**™ once daily, with or without food. Tablets should be swallowed whole.

Side effects
Common side effects of Fezolinetant include:
- stomach (abdominal) pain
- diarrhea
- difficulty sleeping
- back pain
- hot flashes or hot flushes

Stop **Feoza**™ if you have the following signs or symptoms of liver problems:
- nausea
- vomiting
- itching
- yellowing of the eyes or skin (jaundice)
- pale feces
- dark urine
- pain in the right upper stomach (abdomen)

Contraindications
Feoza™ is contraindicated in women with any of the following conditions:
- Known cirrhosis
- Severe renal impairment or end-stage renal disease
- Concomitant use with CYP1A2 inhibitors

Warning & Precaution
Caution should be taken if patient have-
- Hepatic Transaminase Elevation and Hepatotoxicity: Elevations in serum transaminase concentrations greater than 3 times the upper limit of normal (ULN) occurred in the clinical trials. Perform hepatic laboratory tests prior to initiation of Fezolinetant to evaluate for hepatic function and injury. Patient should not start Fezolinetant if the concentration of alanine aminotransferase (ALT) or aspartate aminotransferase (AST) is equal to or exceeds 2 times the ULN or if the total bilirubin is elevated (for example, equal to or exceeds 2 times the ULN) for the evaluating laboratory. Patient should perform follow-up hepatic laboratory tests monthly for the first 3 months, at 6 months, and 9 months after initiation of therapy.

Use in Pregnancy and Lactation
Pregnancy: There are no data on Fezolinetant use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes.
Lactation: There are no data on the presence of Fezolinetant in human milk, the effects on the breastfed child, or the effects on milk production. It is not known if Fezolinetant is present in human milk.

Use in Children & Adolesants
The efficacy and safety of Fezolinetant in individuals less than 18 years of age have not been established.

Drug Interactions
Concomitant use of Fezolinetant with the drugs that are weak, moderate, or strong CYP1A2 inhibitors, increase the plasma Cmax and AUC of Fezolinetant.

Overdosage
Treatment of overdose consists of discontinuation of **Feoza**™ therapy with institution of appropriate symptomatic care.

Storage
Store below 30°C. Keep away from light and out of the reach of children.

How supplied
Each box contains 2 Alu-Alu blister strips of 10 tablets.

Manufactured by
SQUARE
PHARMACEUTICALS PLC.
Gazipur, Bangladesh