

SEVISTA 30

For the use of a Gynecologist only

Abbreviated Prescribing information for SEVISTA 30 (Ormeloxifene 30mg Uncoated Tablet) [Please refer the complete prescribing information for details]

PHARMACOLOGICAL PROPERTIES: Ormeloxifene is a selective estrogen receptor modulator that exerts antiestrogenic effects.

INDICATION: For the treatment of Dysfunctional Uterine Bleeding (DUB) in women of reproductive age groups.

DOSAGE AND ADMINISTRATION: Take 2 tablets (30 mg) twice a week for the 1st 12 week then 2 tablets (30 mg) once a week from 13th week onwards. Take 1st tablet on the 1st day of menstrual cycle.

CONTRAINDICATION: Jaundice or severe hepatic dysfunction or chronic cervicitis or cervical hyperplasia or chronic illnesses like tuberculosis, renal disease, hypersensitivity to ormeloxifene or excipient.

WARNINGS & PRECAUTIONS:

Ormeloxifene has contraceptive properties. Women taking Ormeloxifene for DUB may also experience contraceptive effect. In the event of women desiring the pregnancy, ormeloxifene has to be discontinued. It may take up to a period of 6 months for a woman to conceive after discontinuing ormeloxifene. Women desiring contraception should adhere to the contraceptive schedule. For a period of first 2 months of use a barrier contraceptive must be used in addition to ormeloxifene.

DRUG INTERACTIONS:

Co-administration of tetracycline and lactic acid bacillus spores in the regimen yielded significantly higher C_{max} and a shorter time to reach C_{max} (t_{max}) for ormeloxifene.

ADVERSE REACTIONS:

In clinical trial conducted in forty-two women with menorrhagia the reported adverse effects are ovarian cyst, cervical erosion and discharge, gastric dyspepsia, vague abdominal pain and headache. Because clinical trials are conducted under widely varying conditions, it is not always possible to reliably estimate adverse effects frequency or establish a causal relationship to drug exposure.