Dr.Reddy's

Eranfu®

Fulvestrant 250 mg

For the Treatment of Hormone Positive. Locally Advanced Breast Cancer or Metastatic Breast Cancer[1]

INDICATIONS

☑ Monotherapy :[1]

Treatment of estrogen receptor positive, locally advanced or metastatic breast cancer in postmenopausal women:

- not previously treated with endocrine therapy, or
- with disease relapse on or after adjuvant anti-estrogen therapy, or disease progression on anti-estrogen therapy

☑ Combination :[1]

With palbociclib for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in women who have received prior endocrine therapy

☑ Listed in Approved Drug Products with Therapeutic Equivalence Evaluation (Orange book) from USFDA[2]

Reference
1.Approved Thailand PI Eranfu® version May 28th, 2020
2.ANDA Approval No.A209246

Recommended Dose and Administration[1]

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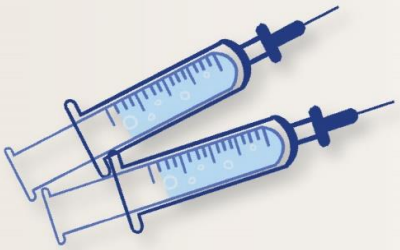
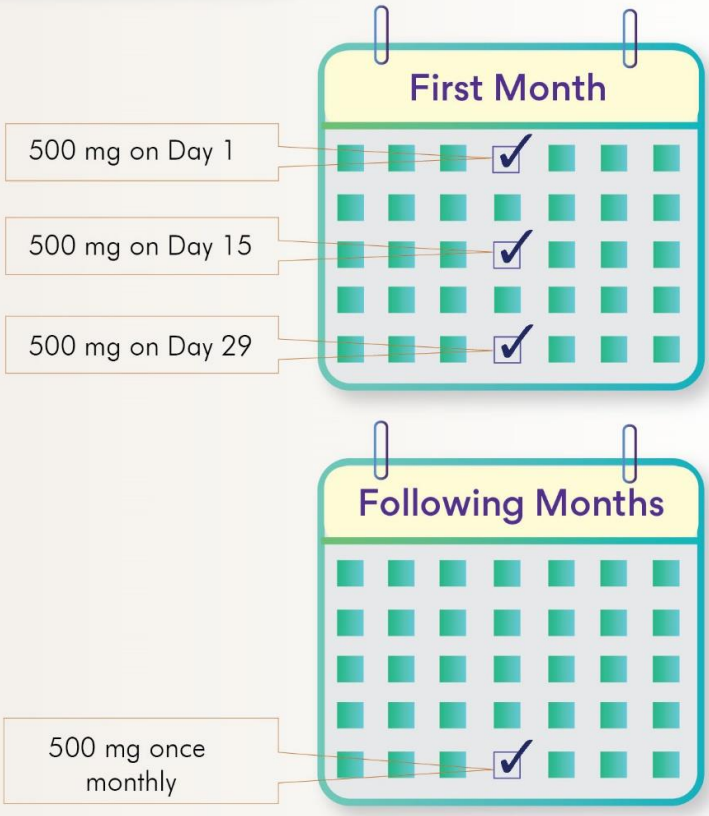


Dosing schedule:

500 mg dose given as
2 x 250 mg/5mL injections

Administration:

Intramuscular injection into the buttocks slowly (1-2 minutes per injection) as two 5mL injections, one in each buttock



ERANFU ® (Fulvestrant) COMPOSITION: Each 5 mL of prefilled syringe contains: Fulvestrant 250 mg. **INDICATIONS:** as monotherapy for the treatment of estrogen receptor positive, locallyadvanced or metastatic breast cancer in postmenopausal women: not previously treated with endocrine therapy, or with disease relapse on or after adjuvant anti-estrogen therapy, or disease progression on anti-estrogen therapy. • in combination with palbociclib for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in women who have received prior endocrine therapy. In pre- or perimenopausal women, the combination treatment with palbociclib should be combined with a luteinizing hormone releasing hormone (LHRH) agonist. **RECOMMENED DOSE:** The recommended dose is 500 mg at intervals of one month, with an additional 500 mg dose given two weeks after the initial dose. **CONTRAINDICATIONS:** Hypersensitivity to the active substance (Fulvestrant), or to any of the excipients e.g. Benzyl alcohol, Alcohol (Ethanol 96%), Benzyl benzoate and Castor oil, Pregnancy and lactation, Severe hepatic impairment. **SPECIAL WARNINGS AND PRECAUTIONS FOR USE:** Fulvestrant should be used with caution: in patients with mild to moderate hepatic impairment, in patientswith severe renal impairment (creatinine clearance < 30 ml/min), in patients with bleeding diatheses, thrombocytopenia or those taking anticoagulant treatment. Thromboembolic events have been observed in clinical studies with fulvestrant. Injection site related events including sciatica, neuralgia, neuropathic pain, and peripheral neuropathy have been reported with fulvestrant injection. Caution should be taken while administering fulvestrant at the dorsogluteal injection site due to the proximity of the underlying sciatic nerve. Due to the mechanism of action of fulvestrant, there is a potential risk of osteoporosis. The efficacy and safety of fulvestrant (either as monotherapy or in combination with palbociclib) have not been studied in patients with critical visceral disease Due tothe structural similarity of fulvestrant and estradiol, fulvestrant may interfere with antibody based-estradiol assays and may result in falsely increased level of estradiol. **PREGNANCY AND LACTATION:** Women of childbearing potential should be advised to use effective contraception while on treatment. Fulvestrant is contraindicated in pregnancy. If pregnancy occurs while taking fulvestrant, the patient must be informed of the potential hazard to the foetus and potential risk for loss of pregnancy.The effects of fulvestrant on fertility in humans has not been studied. **ABILITY TO DRIVE AND USE MACHINES:** Fulvestrant has no or negligible influence on the ability to drive or use machines. However, since asthenia has been reported very commonly with fulvestrant, caution should be observed by those patients who experience this adverse reaction when driving or operating machinery. **ADVERSE REACTIONS:** Fulvestrant monotherapy, the most frequentlyreported adverse reactions were injection site reactions, asthenia, nausea, and increased hepatic enzymes (ALT, AST, The most common (≥ 20%) adverse reactions of any grade reported in patients receiving fulvestrant in combination with palbociclib were neutropenia, leukopenia, infections, fatigue, nausea, anaemia, stomatitis, diarrhoea, and thrombocytopenia. **STORAGE:** Store in a refrigerator (2°C to 8°C). Do not freeze. Store the pre-filled syringe in the original package in order to protect from light.

This is an abridged prescribing information for ERANFU®. It is recommended to refer to the full prescribing information before prescribing. When fulvestrant is combined with palbociclib, please also refer to the prescribing information of palbociclib.

Dr.Reddy's Laboratories Limited Hyderabad 50900,
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DRL/TH/ER-012/May2021

For the use of a registered medical practitioner or a hospital or pharmacy only