BEFORE PRESCRIBING PLEASE REVIEW FULL PRODUCT INFORMATION AVAILABLE ON REQUEST FROM ASTRAZENECA ON 1800 805 342 OR www.astrazeneca.com.au/PI

FASLODEX™ (fulvestrant 250mg/5mL) Minimum Product Information

INDICATIONS: FASLODEX is indicated for the treatment of postmenopausal women with hormone-receptor positive, locally advanced or metastatic breast cancer who have progressive disease following prior tamoxifen therapy.
CONTRAINDICATIONS: Hypersensitivity to the drug substance or any of the excipients. Pregnancy.
PRECAUTIONS: Hepatic impairment – use caution in moderate to severe hepatic impairment, clearance may be reduced. Renal impairment – use caution if creatinine clearance < 30 mL/min. Coagulation disorders – use caution before treating patients with bleeding diatheses or thrombocytopenia or on anticoagulants due to route of administration. Pregnancy - Category D (see CONTRAINDICATIONS). Lactation - avoid. Paediatric use - not recommended. Injection site related events – administer with caution at dorsogluteal injection site due to the proximity of the underlying sciatic nerve - see ADVERSE EFFECTS, DOSAGE & ADMINISTRATION. Driving or operating machinery – asthenia has been reported and caution should be observed. Refer to PI for full information.
INTERACTIONS: Dosage adjustment is not necessary in patients co-prescribed CYP3A4 inhibitors or inducers. No known drug-drug interactions requiring dose adjustment. May interfere with oestradiol assay.
ADVERSE EFFECTS: Very common: Injection site reactions (including sciatica, neuralgia, neuropathic pain, peripheral neuropathy), asthenia, elevated liver enzymes (ALT, AST, ALP), nausea, hypersensitivity reactions, joint & musculoskeletal pain (including arthralgia, back pain, myalgia, pain in extremity), rash, hot flushes. Common: Headache, elevated bilirubin, reduced platelet count, vomiting, diarrhoea, anorexia, urinary tract infections. Others: See full PI.
DOSAGE AND ADMINISTRATION: Do not mix FASLODEX with other drugs. Not recommended in men. Adult females (including the elderly): 500mg administered intramuscularly as two 5 mL injections, one in each buttock, at intervals of 1 month. **Administer with caution at dorsogluteal injection site due to the proximity of the underlying sciatic nerve.* Give additional 500 mg dose 2 weeks after the initial dose. Administer the injection slowly (1-2 minutes/injection). No dose adjustments recommended for patients with creatinine clearance > 30 mL/min or with mild hepatic impairment – see PRECAUTIONS.
PRESENTATION AND STORAGE CONDITIONS: FASLODEX 250 mg/5mL solution in pre-filled syringes (two syringes per pack). Store between 2ºC to 8ºC (in a refrigerator). Store in original pack.

Date of first inclusion in the ARTG: 06 March 2006. Date of most recent amendment: 22 May 2017.

**Please note changes in Product Information.*