ESTROBUILD

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only

Abbreviated Prescribing information for **ESTROBUILD** [Estradiol Valerate Tablets 2 mg] [Please refer the complete prescribing information available at www.torrentpharma.com] **PHARMACOLOGICAL PROPERTIES**: It substitutes for the loss of oestrogen production in menopausal women, and alleviates menopausal symptoms. Oestrogens prevent bone loss following menopause or ovariectomy. Oestrogen deficiency at menopause is associated with an increasing bone turnover and decline in bone mass. The effect of oestrogens on the bone mineral density is dose-dependent. **INDICATION**: Hormone replacement therapy (HRT) for oestrogen deficiency symptoms in peri- and postmenopausal women. Prevention of osteoporosis in postmenopausal women at high risk of future fractures who are intolerant of, or contraindicated for, other medicinal products approved for the prevention of osteoporosis. **DOSAGE AND ADMINISTRATION**: One tablet of Estradiol to be taken daily. It does not matter at what time of day the woman takes her tablet, but once she has selected a particular time she should keep to it every day. Treatment is continuous, which means that the next pack follows immediately without a break. **CONTRAINDICATION:** known, past or suspected breast cancer, known or suspected oestrogen-dependent malignant tumours e.g. endometrial cancer, undiagnosed genital bleeding, untreated endometrial hyperplasia, severe renal disease, previous idiopathic or current venous thromboembolism (deep venous thrombosis, pulmonary embolism) , known thrombophilic disorders (e.g. protein C, protein S, or antithrombin deficiency) active or recent arterial thromboembolic disease e.g. angina, myocardial infarction, acute liver disease, or a history of liver disease as long as liver function tests have failed to return to normal, porphyria and known hypersensitivity to the active substances or to any of the excipients. **WARNINGS & PRECAUTIONS**: Careful monitoring is recommended for patients with congestive heart failure, chronic alcoholism, hepatic dysfunction, or viral infections. Caution should be exercised in patients with cardiac arrhythmias, other cardiovascular diseases, hyperthyroidism or hypertension, gastric and duodenal ulceration or convulsive disorders. Patients with hepatic and renal insufficiency should take it with caution. Caution should be taken while taking estradiol in conditions such as ovarian cancer, ischaemic stroke, coronary artery disease (CAD), venous thromboembolism, breast cancer, endometriosis and carcinoma and migraine. **DRUG INTERACTIONS**: It may interact with cytochrome P450 enzymes, such as anticonvulsants (e.g. phenobarbital, phenytoin, carbamazepine) and anti-infectives (e.g. rifampicin, rifabutin, nevirapine, efavirenz), Ritonavir and nelfinavir, Herbal preparations containing St John's wort, Some laboratory tests may be influenced by oestrogen therapy, such as tests for glucose tolerance or thyroid function. **ADVERSE REACTIONS**: Breast cancer, endometrial cancer, hypersensitivity reaction, exacerbation of hereditary angiooedema, porphyria aggravated, increased or decreased weight, increased appetite, carbohydrate tolerance decreased, anxiety/depressive symptoms, decreased or increased libido, migraine, headache, dizziness, fatigue, chorea, stroke, visual disturbances, intolerance to contact lenses, palpitations, myocardial infarction, hypertension, thrombophlebitis, venous thromboembolism, epistaxis, dyspepsia, abdominal pain, vomiting, nausea, bloating, flatulence, gall bladder disease including cholestasis, rashes, various skin disorders (including pruritus, eczema, urticaria, acne, hirsutism, hair loss, erythema nodosum, erythema multiforme, rash hemorrhagic, chloasma, muscle cramps, leg pain, cystitis-like symptom, increased size of uterine fibroids, vaginal candidosis, uterine cervical erosions, changes in vaginal bleeding pattern and abnormal bleeding or flow, breakthrough bleeding, spotting (bleeding irregularities usually subside during continued treatment), dysmenorrhoea, changes in vaginal secretion, premenstrual-like syndrome, breast secretion, breast tenderness, enlargement or pain and oedema.

MARKETED BY:

TORRENT PHARMACEUTICALS LTD.
Torrent House, Off Ashram Road,
Ahmedabad-380 009, INDIA

IN/ ESTROBUILD 2mg /MAY-2016/01/ABPI

(Additional information is available on request)