

## CESTEL 30

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

Abbreviated Prescribing information for CESTEL 30 (Dienogest and Ethinylestradiol Tablets)

[Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com)]

### PHARMACOLOGICAL PROPERTIES:

**Mechanism of action:** The primary mechanisms are ovulation (by suppression of gonadotrophins) and changes in the cervical secretion (blocking the entry of sperm into the uterus). For the majority of users, the cycle is more regular, the menstruation is often less painful and bleeding is lighter. The latter may result in a decrease in the occurrence of iron deficiency. Dienogest has beneficial properties in addition to contraception. Dienogest exerts antiandrogenic activity leading to a positive effect on the skin and to a reduction in acne lesions and sebum production.

**DOSAGE AND ADMINISTRATION:** One tablet is to be taken daily for 21 consecutive days.

### CONTRAINDICATION:

Presence or risk of venous thromboembolism (VTE): such as APC-resistance (including Factor V Leiden), antithrombin-III-deficiency, protein C deficiency, protein S deficiency. Presence or risk of arterial thromboembolism (ATE): Known hereditary or acquired predisposition for arterial thromboembolism, such as hyperhomocysteinaemia and antiphospholipid-antibodies (eg. anticardiolipinantibodies and lupus anticoagulant, diabetes mellitus with vascular symptoms, severe hypertension, dyslipoproteinaemia, Pancreatitis, use of direct-acting antiviral (DAA) medicinal products, sex-steroid influenced malignancies, Undiagnosed vaginal bleeding, Known or suspected pregnancy. Hypersensitivity to the active substance or to any of the excipients.

**WARNINGS & PRECAUTIONS:** Increased risk of arterial and venous thrombotic and thromboembolic diseases such as myocardial infarction, stroke, deep venous thrombosis and pulmonary embolism, Risk of venous thromboembolism (VTE), arterial thromboembolism (ATE), Tumours, women with hypertriglyceridaemia have higher risk of pancreatitis, Crohn's disease and ulcerative colitis, does not protect against Sexually transmitted infections (STIs) including Human Immunodeficiency Virus (HIV) infections and AIDS.

**ADVERSE REACTIONS:** Deep venous thrombosis, pulmonary embolism, cerebral infarction, thrombosis, migraine, stroke, occlusion retinal artery, hepatic haemangioma, superficial thrombophlebitis, hypertension, peripheral vascular disease, intermenstrual bleeding (consisting of vaginal haemorrhage and metrorrhagia), menstrual disorders, vaginal mycosis, nausea, vomiting, diarrhoea, cholelithiasis, liver neoplasm, fatty liver, pancreatitis, hepatitis, hepatic cyst, decreased cholinesterase, gingivitis and abdominal pain (including upper and lower abdominal pain, abdominal discomfort/distention), depression, mood altered, headache, migraine, galactorrhoea, paresthesia, articular swelling, voice alteration, dyspnoea, asthma, dermatitis, rash, urticaria, erythema nodosum, erythema multiforme, atopic eczema (exacerbation), papulous exanthema, chloasma, contact lens intolerance, blurred vision, hypertriglyceridemia, oedema, change in weight, fluid retention, haemorrhagic purpura, leucopenia, anaphylactic reaction, pain in extremities, breast pain (including breast discomfort and breast tenderness), hypertrophy breast and breast discharge.

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TORRENT PHARMACEUTICALS LTD.

**IN/CESTEL 2mg,30 mcg/SEP-20/01/ABPI**  
(Additional information is available on request)