

NEWVEN OD

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

Abbreviated Prescribing information for NEWVEN OD [Desvenlafaxine Extended-Release Tablets 50 / 100 mg]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: The exact mechanism of the antidepressant action of desvenlafaxine is unknown but is thought to be related to the potentiation of serotonin and norepinephrine in the central nervous system, through inhibition of their reuptake. Non-clinical studies have shown that desvenlafaxine is a potent and selective serotonin and norepinephrine reuptake inhibitor (SNRI).

INDICATIONS: Desvenlafaxine used for the treatment of major depressive disorder (MDD)

DOSAGE AND ADMINISTRATION: The recommended dose for desvenlafaxine extended-release tablets are 50 mg once daily, with or without food. The 50 mg dose is both a starting dose and the therapeutic dose. Desvenlafaxine extended-release tablets should be taken at approximately the same time each day. Tablets must be swallowed whole with fluid and not divided, crushed, chewed, or dissolved

CONTRAINDICATION: Hypersensitivity to desvenlafaxine succinate, venlafaxine hydrochloride or to any excipients in the desvenlafaxine formulation. Angioedema has been reported in patients treated with desvenlafaxine. The use of MAOIs intended to treat psychiatric disorders with desvenlafaxine or within 7 days of stopping treatment with desvenlafaxine is contraindicated because of an increased risk of serotonin syndrome. The use of desvenlafaxine within 14 days of stopping an MAOI intended to treat psychiatric disorders is also contraindicated. Starting desvenlafaxine in a patient who is being treated with MAOIs such as linezolid or intravenous methylene blue is also contraindicated because of an increased risk of serotonin syndrome

WARNINGS & PRECAUTIONS: Patients with MDD, both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior, whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs. Suicide is a known risk of depression and certain other psychiatric disorders, and these disorders themselves are the strongest predictors of suicide

DRUG INTERACTIONS: False-positive urine immunoassay screening tests for phencyclidine (PCP) and amphetamine have been reported in patients taking desvenlafaxine. This is due to lack of specificity of the screening tests. False positive test results may be expected for several days following discontinuation of desvenlafaxine therapy. Confirmatory tests, such as gas chromatography/mass spectrometry, will distinguish desvenlafaxine from PCP and amphetamine

ADVERSE REACTIONS: Hypersensitivity, suicidal thoughts, serotonin syndrome, elevated blood pressure, increased risk of bleeding, angle closure glaucoma, discontinuation syndrome, seizure, hyponatremia, interstitial lung disease and eosinophilic pneumonia, sexual dysfunction, hot flush, vertigo, mydriasis, vision blurred, yawning, tinnitus, Stevens-Johnson syndrome, Takotsubo cardiomyopathy Anosmia, hyposmia.

MARKETED BY:

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PHARMA

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(Additional information is available on request)