

NEWVEN OD

For the use of a Psychiatrist 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: Desvenlafaxine is the major active metabolite of the antidepressant venlafaxine, a medication used to treat major depressive disorder. 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. **INDICATIONS:** For the treatment of major depressive disorder. **DOSAGE AND ADMINISTRATION:** 50 mg a day. People with liver disease should not take more than 100 mg per day. **CONTRAINDICATION:** Hypersensitivity to desvenlafaxine or to any excipients in the Desvenlafaxine. Angioedema has been reported. The use of Monoamine Oxidase Inhibitors (MAOIs) with Desvenlafaxine is contraindicated because of an increased risk of serotonin syndrome. Starting Desvenlafaxine in a patient who is being treated with MAOIs such as linezolid or intravenous methylene blue is also contraindicated. **WARNINGS & PRECAUTIONS: Suicidal Thoughts and Behaviors in Adolescents and Young Adults:** May experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior. May increase the risk of bleeding events. **Serotonin Syndrome:** Symptoms may include mental status changes (e.g., agitation, hallucinations, delirium, and coma), autonomic instability (e.g., tachycardia, labile blood pressure, dizziness, diaphoresis, flushing, hyperthermia), neuromuscular symptoms (e.g., tremor, rigidity, myoclonus, hyperreflexia, incoordination), seizures, and/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea). **Elevated Blood Pressure:** Should have regular monitoring of blood pressure since increases in blood pressure were observed in clinical studies. **Abnormal Bleeding:** May increase the risk of bleeding events. **Angle-Closure Glaucoma:** The pupillary dilation that occurs following the use of many antidepressant drugs including Desvenlafaxine may trigger an angle closure attack in a patient with anatomically narrow angles who does not have a patent iridectomy. **Activation of mania/hypomania.** **Discontinuation Syndrome:** Abrupt discontinuation or dose reduction has been associated with the appearance of new symptoms that include dizziness, nausea, headache, irritability, insomnia, diarrhea, vomiting, anxiety, fatigue, abnormal dreams, and hyperhidrosis. Hyponatremia may occur. Interstitial lung disease and eosinophilic pneumonia associated have been rarely reported. **DRUG INTERACTIONS:** Monoamine Oxidase Inhibitors (MAOIs); Serotonergic Drugs; Drugs that Interfere with Hemostasis (e.g., NSAIDs, Aspirin, and Warfarin); **Potential for Desvenlafaxine to Affect Other Drugs:** Dosage adjustment may require for Substrates primarily metabolized by CYP2D6 like desipramine, atomoxetine, dextromethorphan, metoprolol, nebivolol, perphenazine, tolterodine. **Other Drugs Containing Desvenlafaxine or Venlafaxine:** The concomitant use will increase desvenlafaxine blood levels and increase dose-related adverse reactions. **Ethanol:** patients should be advised to avoid alcohol consumption while taking Desvenlafaxine. **ADVERSE REACTIONS:** Nausea, dizziness, insomnia, hyperhidrosis, constipation, somnolence, decreased appetite, anxiety, specific male sexual function disorders including Libido decreased, Musculoskeletal stiffness, Depersonalization, bruxism, Orgasm abnormal, Ejaculation delayed, Erectile dysfunction, Ejaculation disorder, Ejaculation failure, Sexual dysfunction and Anorgasmia in women, Blood pressure increased, Dry mouth, Fatigue, Chills, Feeling jittery, Tremor, Disturbance in attention, Nervousness, Urinary hesitation, Yawning, Vision blurred, Mydriasis, Vertigo, Tinnitus, Dysgeusia, Rash, alopecia, photosensitivity reaction, Hot flush, Proteinuria, Orthostatic hypotension, Syncope, convulsion, dystonia and Stevens-Johnson syndrome.

MARKETED BY:



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(Additional information is available on request)