



Nikita[®] (pitavastatin) – New drug approval

- On August 4, 2017, the [FDA approved](#) Lupin's [Nikita \(pitavastatin\)](#) as an adjunctive therapy to diet to reduce elevated total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo B), triglycerides (TG), and to increase high-density lipoprotein cholesterol (HDL-C) in adult patients with primary hyperlipidemia or mixed dyslipidemia.
 - Doses of Nikita > 4 mg once daily were associated with an increased risk for severe myopathy in premarketing clinical studies. Daily doses should not exceed 4 mg.
 - The effect of Nikita on cardiovascular morbidity and mortality has not been determined.
 - Nikita has not been studied in Fredrickson Type I, III, and V dyslipidemias.
- Pitavastatin is also available as [Livalo[®]](#) and recently approved [Zypitamag[™]](#).
 - Livalo and Zypitamag carry the same indication as Nikita.
 - Similar to Livalo and Zypitamag, Nikita will be available as 1 mg, 2 mg, and 4 mg tablets.
- The efficacy of Nikita was based on the clinical trials conducted for Livalo.
 - Pitavastatin, given as a single daily dose for 12 weeks, significantly reduced plasma LDL-C, TC, TG, and Apo-B vs. placebo and was associated with variable increases in HDL-C across the dose range.
 - For the percent change from baseline to endpoint in LDL-C, pitavastatin was non-inferior to [atorvastatin](#) and [simvastatin](#) for comparable doses.
 - Pitavastatin significantly reduced LDL-C vs. [pravastatin](#) at comparable doses.
- Nikita is contraindicated in patients with active liver disease which may include unexplained persistent elevations of hepatic transaminase levels, co-administration with [cyclosporine](#), during pregnancy, during lactation, and in patients with a known hypersensitivity to any component of pitavastatin.
- Warnings and precautions of Nikita include skeletal muscle effects, liver enzyme abnormalities, and endocrine function.
- The most common adverse reactions (≥ 2% in at least one marketed dose) with Nikita use were myalgia, back pain, diarrhea, constipation, and pain in extremity.
- The recommended starting dosage of Nikita is 2 mg orally once daily.
 - The dose range of Nikita is 1 mg to 4 mg orally once daily.
 - The starting dose and maintenance doses of Nikita should be individualized according to patient characteristics, such as goal of therapy and response.
 - After initiation or upon titration of Nikita, lipid levels should be analyzed after 4 weeks and the dosage adjusted accordingly.
- Lupin's launch plans for Nikita are pending.



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