

Management of Statin Intolerance and Combined Dyslipidemia with a Monacolin K-Free Nutraceutical Formulation (LopiGLIK® BIO): A Clinical Case Report

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Received: September 30, 2026 | Published: October 07, 2026

How to cite this article:

Trimarco B. Management of Statin Intolerance and Combined Dyslipidemia with a Monacolin K-Free Nutraceutical Formulation (LopiGLIK® BIO): A Clinical Case Report. *J Case Rep Rev Med.* 2026;2(4):1-2. doi:10.64978/jcrrm.2026.10070134.

Abstract

Statin intolerance represents a significant clinical challenge in cardiovascular disease prevention, often leading to therapy discontinuation and uncontrolled lipid levels. Monacolin K-free nutraceuticals provide an alternative therapeutic strategy for lipid and glucose management without statin-related side effects. We report the case of a 58-year-old male with moderate hypercholesterolemia, impaired fasting glucose, and a history of statin-associated muscle symptoms (SAMS). After discontinuing statin therapy due to severe myalgia and elevated creatine kinase levels, the patient was started on a daily oral formulation of **LopiGLIK® BIO** — a nutraceutical containing *Trigonella foenum-graecum* (fenugreek), *Morus alba*, and Niacin. After 12 weeks of treatment, the patient showed a significant improvement in lipid levels, with a 22% reduction in low-density lipoprotein cholesterol (LDL-C) and a 19% reduction in total cholesterol, along with stabilized fasting plasma glucose, without experiencing any muscular or gastrointestinal adverse effects. This case highlights the clinical utility and safety of a monacolin K-free nutraceutical combination in managing cardiovascular risk in statin-intolerant patients.

Keywords: Statin Intolerance; Dyslipidemia; LopiGLIK BIO; Nutraceuticals; Fenugreek; *Morus alba*; Monacolin K-free.

1. Introduction

Elevated low-density lipoprotein cholesterol (LDL-C) remains a primary modifiable risk factor for coronary artery disease and cardiovascular events.¹ While HMG-CoA reductase inhibitors (statins) are the cornerstone of lipid-lowering therapy, statin-associated muscle symptoms (SAMS) affect a non-negligible proportion of patients, leading to non-adherence or treatment discontinuation.²

Furthermore, emerging evidence suggests that controlling both glycemia and lipid profiles simultaneously yields greater overall cardiovascular protection.³ Red yeast rice derivatives containing monacolin K have been widely used as natural alternatives; however, monacolin K shares the same chemical structure as lovastatin and can trigger similar adverse muscle reactions in sensitive individuals.

LopiGLIK® BIO is an innovative, monacolin K-free oral formulation (15 mL vials) combining *Trigonella foenum-graecum* (fenugreek), *Morus alba* (white mulberry), and Niacin. *Trigonella*

foenum-graecum supports lipid metabolism, significantly lowering LDL-C and total cholesterol; *Morus alba* inhibits carbohydrate absorption and improves glucose homeostasis; and Niacin contributes to normal energy-yielding metabolism and cardiovascular risk reduction. We present a case of a statin-intolerant patient successfully treated with **LopiGLIK® BIO**.

2. Case Presentation

A 58-year-old male patient with a history of mild hypertension and moderate dyslipidemia presented to our outpatient clinic for cardiovascular risk management. His previous therapy included Atorvastatin 20 mg/day, which was discontinued four weeks prior due to severe bilateral thigh myalgia and persistent weakness. Laboratory testing at that time revealed elevated serum creatine kinase (CK) levels (380 U/L; normal range < 190 U/L).

Upon presentation, the physical examination was unremarkable (BMI: 27.4 kg/m²; Blood Pressure: 128/82 mmHg). Baseline laboratory evaluation showed:

- Total Cholesterol: 245 mg/dL

- LDL-C: 162 mg/dL
- HDL-C: 44 mg/dL
- Triglycerides: 195 mg/dL
- Fasting Plasma Glucose (FPG): 108 mg/dL
- HbA1c: 5.9%
- Creatine Kinase (CK): Normalised (115 U/L)

Given the patient's complete intolerance to statins and his preference for a natural, non-statin approach, lifestyle modification (Mediterranean diet and moderate exercise) was reinforced, and treatment with **LopiGLIK® BIO** (1 oral vial of 15 mL once daily) was initiated.

3. Results / Follow-up

The patient tolerated the therapy exceptionally well, reporting full adherence and no recurrent muscular symptoms or gastrointestinal discomfort.

At the 12-week follow-up, laboratory reassessment showed significant metabolic improvements:

- Total Cholesterol: 198 mg/dL (19.2% reduction)
- LDL-C: 126 mg/dL (22.2% reduction)
- Triglycerides: 160 mg/dL (17.9% reduction)
- HDL-C: 46 mg/dL
- Fasting Plasma Glucose: 96 mg/dL

Table 1:

Parameter	Baseline	Week 12	Change (%)
Total Cholesterol (mg/dL)	245	198	-19.2%
LDL-C (mg/dL)	162	126	-22.2%
Triglycerides (mg/dL)	195	160	-17.9%
Fasting Glucose (mg/dL)	108	96	-11.1%

4. Discussion

Managing cardiovascular risk in patients with statin intolerance requires effective, well-tolerated alternatives. Monacolin K, although natural, poses risks similar to statins in individuals prone to SAMS. Therefore, monacolin K-free formulations represent a safer lipid-lowering option.

In this case, **LopiGLIK® BIO** demonstrated clinical efficacy comparable to preliminary clinical evaluations (which show approximately a 20% reduction in total cholesterol and 25% in LDL-C).

The synergistic action of its active components contributed to this comprehensive response:

1. **Trigonella foenum-graecum**: Systematic review and meta-analysis data confirm its significant lipid-lowering effect on total cholesterol, LDL-C, and triglycerides.⁵
2. **Morus alba**: Contributes to carbohydrate metabolism regulation by reducing postprandial glucose spikes and improving insulin sensitivity.⁶
3. **Niacin**: Enhances lipid profiles and energy metabolism, aligning with observational studies showing cardiovascular benefit from niacin intake.⁴

The liquid formulation (single 15 mL vial per day) also facilitated excellent patient compliance and satisfaction.

5. Conclusion

LopiGLIK® BIO offers a safe, effective, and well-tolerated option for lipid and glycemic management in subjects with statin intolerance or muscle sensitivity. The combination of *Trigonella foenum-graecum*, *Morus alba*, and Niacin addresses both lipid and carbohydrate metabolic pathways without triggering statin-like muscular adverse effects. Long-term clinical trials are encouraged to confirm these findings in broader populations.

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