Indications

NIASPAN® (niacin extended-release tablets) is indicated as an adjunct to diet when the response to a diet restricted in saturated fat and cholesterol and other nonpharmacologic measures alone has been inadequate, to reduce elevated TC, LDL-C, Apo B, and TG levels, and to increase HDL-C in patients with primary hypercholesterolemia (heterozygous familial and nonfamilial) and mixed dyslipidemia (Fredrickson Types IIa and IIb). In patients with a history of: myocardial infarction and hypercholesterolemia, niacin is indicated to reduce the risk of recurrent nonfatal myocardial infarction or; coronary artery disease and hypercholesterolemia, niacin, in combination with a bile acid binding resin, is indicated to slow progression or promote regression of atherosclerotic disease.

NIASPAN in combination with lovastatin is indicated for the treatment of primary hypercholesterolemia (heterozygous familial and nonfamilial) and mixed dyslipidemia (Fredrickson Types IIa and IIb) in patients treated with: lovastatin who require further TG lowering or HDL-C raising who may benefit from having niacin added to their regimen or; niacin who require further LDL-C lowering who may benefit from having lovastatin added to their regimen.

Combination therapy is not indicated for initial therapy.

Important Safety Information

NIASPAN is contraindicated in patients with a known hypersensitivity to niacin or any component of this medication, significant or unexplained hepatic dysfunction, active peptic ulcer disease, or arterial bleeding.

NIASPAN preparations should not be substituted for equivalent doses of immediate-release (crystalline) niacin. For patients switching from immediate-release niacin to NIASPAN, therapy with NIASPAN® should be initiated with low doses (i.e., 500 mg qhs) and the NIASPAN dose should then be titrated to the desired therapeutic response.

Cases of severe hepatic toxicity, including fulminant hepatic necrosis, have occurred in patients who have substituted sustained-release (modified-release, timed-release) niacin products for immediate-release (crystalline) niacin at equivalent doses.

Active liver diseases or unexplained transaminase elevations are contraindications to the use of NIASPAN. NIASPAN should be used with caution in patients who consume substantial quantities of alcohol and/or have a past history of liver disease.

Liver tests should be performed on all patients during therapy with NIASPAN. Serum transaminase levels should be monitored before treatment begins, every 6 to 12 weeks for the first year, and periodically thereafter.

Rare cases of rhabdomyolysis have been associated with concomitant administration of lipid-altering doses (≥1 g/day) of niacin and HMG-CoA reductase inhibitors. **Patients on combined therapy with HMG-CoA reductase inhibitors and NIASPAN should be monitored carefully for any signs and symptoms of muscle pain, tenderness, or weakness particularly during the initial months of therapy and during any periods of upward dosage titration of either drug.** Periodic serum creatine phosphokinase (CPK) and potassium determinations should be considered in such situations, but there is no assurance that such monitoring will prevent the occurrence of severe myopathy.

Diabetic patients may experience a dose-related rise in glucose intolerance, the clinical significance of which is unclear. Diabetic or potentially diabetic patients should be observed closely. Adjustment of diet and/or hypoglycemic therapy may be necessary.

The most common adverse event with NIASPAN is flushing (up to 88% in placebo-controlled trials; <6% of patients discontinued). Flushing is a redness, warmth, itching, and/or tingling sensation on the face, neck, chest, and/or back. Spontaneous reports suggest that flushing may also be accompanied by dizziness, tachycardia, palpitations, shortness of breath, sweating, chills, and/or edema, which in rare cases may lead to syncope. Other common adverse events (≥5% patients) include: headache, pain, diarrhea, dyspepsia, nausea, vomiting, abdominal pain, rhinitis, rash, and itching.

References: 1. Data on file, Kos Pharmaceuticals, Inc., Cranbury, NJ 08512. **2.** NIASPAN® prescribing information. North Chicago, Ill: Abbott Laboratories. **3.** Brown G, Albers JJ, Fisher LD, et al. Regression of coronary artery disease as a result of intensive lipid-lowering therapy in men with high levels of apolipoprotein B. *N Engl J Med.* 1990;323:1289-1298. **4.** Blankenhorn DH, Nessim SA, Johnson RL, Sanmarco ME, Azen SP, Cashin-Hemphill L. Beneficial effects of combined colestipol-niacin therapy on coronary atherosclerosis and coronary venous bypass grafts. *JAMA.* 1987;257:3233-3240. **5.** The Coronary Drug Project Research Group. Clofibrate and niacin in coronary heart disease. *JAMA.* 1975;231:360-381. **6.** Mosca L, Banka CL, Benjamin EJ, et al, for the Expert Panel/Writing Group. AHA guidelines. Evidence-based guidelines for cardiovascular disease prevention in women: 2007 update. *Circulation.* 2007;115:1-21.

Please see accompanying full Prescribing Information.

Tip PI here (1.125" x 3")
DO NOT PRINT

NEW Coated Tablets
NIASPAN® niacin EXTENDED-RELEASE TABLETS
Raise. Regress. Reduce.

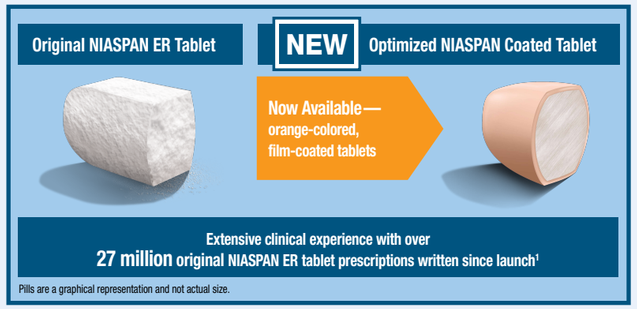
Abbott
A Promise for Life

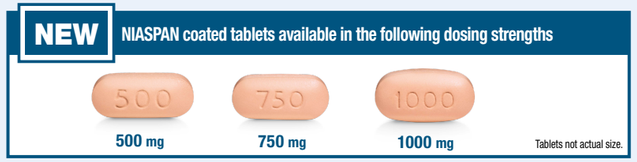
NEW Coated Tablets
NIASPAN® niacin EXTENDED-RELEASE TABLETS
Raise. Regress. Reduce.

Niaspan Coated Tablets

Introducing...

A new, coated tablet with the same proven benefits





NEW NIASPAN COATED TABLET

- **1000-mg tablet is now dry-mixed, directly compressed, and then film-coated**
  - **One 1000-mg coated tablet is bioequivalent to two 500-mg coated tablets**
    - **1 vs 2 tablets may enhance convenience**
    - **May make titration to the 1000-mg dose easier**
- **In a pharmacokinetic study of healthy volunteers, the extent of absorption between the 1000-mg coated tablet and the original 1000-mg tablet was the same. However, the rate of absorption was slower with the 1000-mg coated tablet[1]**
- **New film coating applied to all dosing strengths—500 mg, 750 mg, and 1000 mg**

Please see Indications and Important Safety Information on back cover.
Please see accompanying full Prescribing Information.

Abbott
A Promise for Life

NIASPAN® (niacin) helps take patients in the right direction

Shown to significantly RAISE HDL-C

- NIASPAN monotherapy at doses of 1000 mg and 2000 mg significantly raised HDL-C 18% and 22% from baseline ($P<0.05$ vs placebo)[2]
- NIASPAN 1000 mg + lovastatin 40 mg combination therapy significantly raised HDL-C 20% from baseline ($P<0.05$ vs NIASPAN and lovastatin monotherapy)[2]

Promotes the REGRESSION of atherosclerosis*

In patients with established coronary artery disease (CAD):

- 39% of patients taking niacin + colestipol, with dietary counseling, experienced significant regression from baseline ($P<0.005$ vs placebo) after 2.5 years of follow-up in the FATS study†[2,3]
  - 25% of patients taking niacin + colestipol experienced progression[2,3]
- After 2 years, disease regression occurred more frequently in patients receiving niacin + colestipol vs placebo (16% vs 2%; $P=0.002$; n=162) in the CLAS study‡[2,4]
  - 39% of patients taking niacin + colestipol showed disease progression compared with 61% of patients taking placebo ($P<0.005$)[2,4]

REDUCES the risk of recurrent, nonfatal MI§

- In patients with a history of myocardial infarction (MI), niacin significantly reduced the incidence of recurrent, nonfatal MI 27% vs placebo after 5 years ($P<0.004$)[5]
- Though not an original endpoint of the FATS trial, clinical events (death, MI, or revascularization for worsening angina) occurred in 10 of 52 patients who received conventional therapy compared with 2 of 48 who received niacin + colestipol[2]

*In patients with a history of CAD and hypercholesterolemia, niacin, in combination with a bile acid binding resin, is indicated to slow progression or promote regression of atherosclerotic disease.

†FATS = Familial Atherosclerosis Treatment Study.[3]

‡CLAS = Cholesterol-Lowering Atherosclerosis Study.[4]

§In patients with a history of MI and hypercholesterolemia, niacin is indicated to reduce the risk of recurrent, nonfatal MI.

Please see Important Safety Information on back cover. Please see accompanying full Prescribing Information.

Pharmacy counseling tips

Patient counseling tips

- Always **take your medications as directed** by your physician
- **Do not discontinue taking NIASPAN without talking to your physician**
- Take NIASPAN **with a low-fat snack**
- Notify physician **if taking vitamins containing niacin**
- **In diabetics,** notify physician of changes in blood sugar
- NIASPAN tablets should not be broken, crushed, or chewed but **should be swallowed whole**

Simple tips to help patients manage flushing

Take aspirin or a nonsteroidal anti-inflammatory drug (eg, ibuprofen) approximately 30 minutes prior to the NIASPAN dose.

Take NIASPAN at bedtime.

Avoid hot or alcoholic beverages near the time of taking NIASPAN.

The American Heart Association states that "dietary supplement" niacin must not be used as a substitute for prescription niacin."[6]

Visit www.niaspan.com

Titrate NIASPAN for optimal dosing

Weeks 1-4 → **INITIATE with one 500-mg tablet**

Weeks 5-8 → **TITRATE to one 1000-mg tablet**

After week 8, titrate to patient response and tolerance*

If not at goal → **Increase to 1500 mg**

If not at goal → **Increase to 2000 mg**

Take all tablets at bedtime.

*If response to 1000 mg daily is inadequate, increase dose to 1500 mg daily; may subsequently increase dose to 2000 mg daily. Daily dose should not be increased more than 500 mg in a 4-week period, and doses above 2000 mg daily are not recommended.