Shown to significantly RAISE HDL-C

- Up to 22% with 2000 mg NIASPAN as monotherapy*[1]
- 20% with NIASPAN 1000 mg + lovastatin 40 mg in combination†[1]

Promotes the REGRESSION of atherosclerosis

In patients with established coronary artery disease (CAD):

- Significant regression after 2.5 years in 39% of patients taking niacin + colestipol in the FATS study‡[1,2]
- More frequent disease regression after 2 years in patients taking niacin + colestipol vs placebo (16% vs 2%; *P*=0.002) in the CLAS study§[1,3]

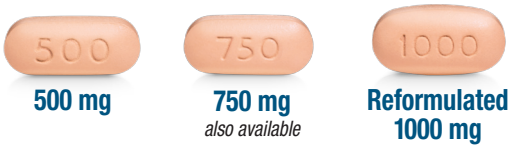
REDUCES the risk of recurrent nonfatal MI

In patients with a history of MI:

- Significantly reduced the incidence of recurrent nonfatal MI by 27% after 5 years in patients taking niacin‖[1,4]

NIASPAN Coated Tablets

- 1000-mg coated tablet has been reformulated
- All dosing strengths are film coated—500 mg, 750 mg, and 1000 mg



500 mg | 750 mg *also available* | Reformulated 1000 mg

NIASPAN Coated Tablets shown not actual size.
DO NOT break, crush, or chew NIASPAN tablets.

*Results with NIASPAN 2000 mg vs placebo ($P<0.05$).
†Results with NIASPAN 1000 mg + lovastatin 40 mg vs NIASPAN and lovastatin monotherapy ($P<0.05$).
‡Follow-up results from the FATS study showing regression from baseline vs placebo ($P<0.005$).
§Results from the CLAS study showing frequency of disease regression.[1,3]
‖Results vs placebo ($P<0.004$).

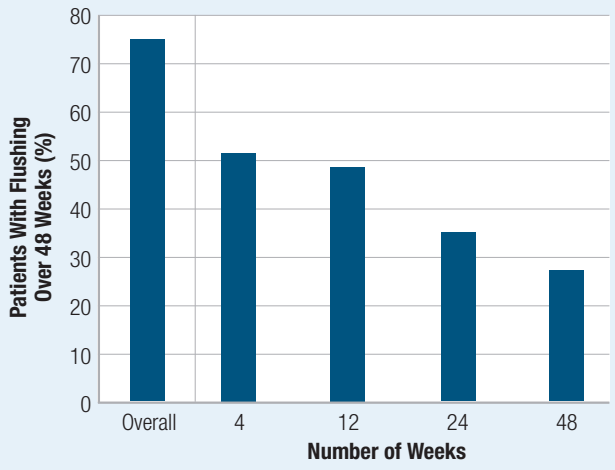
COATED TABLETS
NIASPAN®
niacin EXTENDED-RELEASE TABLETS
Raise. Regress. Reduce.

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

Abbott
A Promise for Life

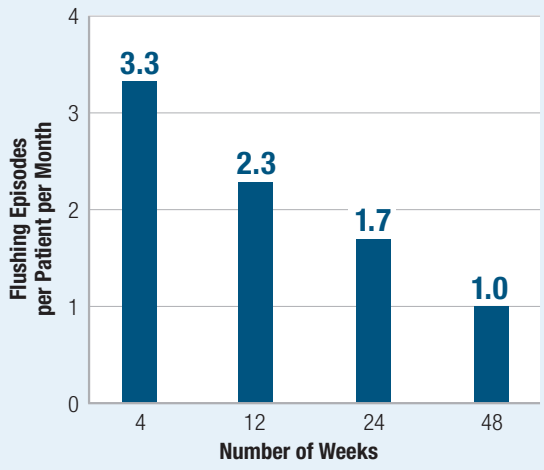
Flushing events decreased over time in a long-term study[5]

Occurrence of flushing with NIASPAN® decreased over time[5]



50% of patients did not experience flushing after Week 12

Frequency of flushing also decreased over time*[5]



Flushing decreased from 3.3 episodes to 1 episode per patient per month*

*In patients who experienced flushing.

Flushing results from an open-label study done to assess the long-term safety and efficacy of NIASPAN taken once nightly by patients with primary hypercholesterolemia. Safety data included adverse events and laboratory data from 723 patients over a 2-year period. All patients entering this extension trial were previously enrolled in randomized, shorter-term studies or in a placebo-only qualification clinical trial. The NIASPAN median dosage was 2000 mg daily. Aspirin 325 mg taken 30 minutes before dosing could be utilized for prophylaxis and treatment of flushing. About one-third of patients used aspirin to minimize flushing episodes.

Nearly one-third of patients in this study took 325 mg of aspirin prior to NIASPAN dosing to help minimize flushing.[5]

Flushing events with original NIASPAN ER tablets[1]

- Most patients taking original NIASPAN experience flushing
  – In clinical trials, 88% of patients experienced flushing; <6% of patients discontinued
- Flushing varies in intensity, is mild to moderate in most patients, and typically abates over several weeks
- 78% fewer flushing episodes with the original NIASPAN 1500 mg qhs vs immediate-release (IR) niacin 500 mg tid occurred during 4 weeks of maintenance therapy
  – The incidence of flushing over the 4-week period averaged 8.56 events per patient for IR niacin vs 1.88 events following NIASPAN

Pharmacist Counseling Tips

Prepare your patients to help manage flushing and GI upset

Simple tips to help manage flushing...

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

Take NIASPAN at bedtime.

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

...and minimize GI upset

Take NIASPAN with a low-fat snack.

Additional Counseling Tips

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

Visit www.niaspan.com

Titrate NIASPAN ER Coated Tablets for optimal response

Weeks 1-4	**INITIATE** with 500-mg tablet
Weeks 5-8	**TITRATE** to reformulated 1000-mg tablet
After Week 8...	**TITRATE** to patient response and tolerance*
If not at goal...	**INCREASE** to 1500-mg dose
If still not at goal...	**INCREASE** to 2000-mg dose

- Take 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.

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

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
- In patients with a history of 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. NIASPAN® [prescribing information]. North Chicago, IL; Abbott Laboratories, 2007. **2.** 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. **3.** 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. **4.** The Coronary Drug Project Research Group. Clofibrate and niacin in coronary heart disease. *JAMA.* 1975;231:360-381. **5.** Capuzzi DM, Guyton JR, Morgan JM, et al. Efficacy and safety of an extended-release niacin (Niaspan): a long-term study. *Am J Cardiol.* 1998;82:74U-81U. **6.** Mosca L, Banka CL, Benjamin EJ, et al, for the Expert Panel/Writing Group. Evidence-based guidelines for cardiovascular disease prevention in women: 2007 update. *Circulation.* 2007;115:1-21.

Full Prescribing Information is available at http://www.RxAbbott.com/pdf/niaspan.pdf

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