



ADVICOR (niacin extended-release/lovastatin) tablets

Patient Advisory Label Update®

DRUG NAME: ADVICOR (niacin extended-release/lovastatin) tablets

MANUFACTURER: Kos Pharmaceuticals

INDICATIONS FOR USE: For the treatment of primary hypercholesterolemia (helps to lower levels of cholesterol in the blood).

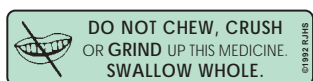
Specialty Label for Advicor:



Pharmacist: Please affix to each Advicor prescription you dispense. The purpose of this label is to inform the patient about a special phone number to obtain more information about flushing.

In order to assist you with your patient counseling, we recommend the use of the following Patient Advisory Label(s) when you dispense Advicor:

A-31:



Research: Package insert states: "tablets should be taken whole and should not be broken, crushed, or chewed before swallowing." This tablet releases medication over a period of time.

A-56:



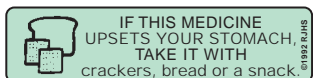
Research: Flushing is listed as a side effect in the package insert with an occurrence rate of greater than 50%. This label was produced to advise the patient to seek professional advice from their doctor or pharmacist if flushing does occur and is bothersome.

A-57:



Research: The package insert specifically states, "Do not drink grapefruit juice around the time you take Advicor". Upon further research, we find that grapefruit juice may enhance certain side effects or cause additional side effects.

A-29:



Research: This medication should be taken with a low-fat snack (banana; low fat yogurt; crackers or slice of bread with a glass of low-fat milk) to help reduce the chance of upset stomach.

A-9:



Research: A patient's diet is the most important part of controlling their condition and is necessary for this medication to work properly. If the patient's physician has suggested a diet, stress the need to follow it.

Please Note: The Patient Advisory Label Update® and The Patient Advisor® are intended to provide the healthcare professional with easily accessible, practical drug counseling information to use when verbally communicating with a patient about a particular drug. The information printed here is designed to assist, not replace, professional judgement. The author, manufacturer or distributor make no claims regarding proper use of this information.

References available upon request.

To obtain Labels or other Patient Counseling Information:



R•J Health Systems, Inc.

P.O. Box 290616 • Wethersfield, CT 06109 • Phone: 860-563-1223 Fax: 860-563-1650 • or on the web: www.rjhealthsystems.com



ADVICOR (niacin extended-release/lovastatin) tablets

Patient Advisor[®]

Be sure to read all this information and contact your doctor or pharmacist if you have any questions that are not answered here.

THIS MEDICATION IS USED:

To treat abnormal levels of cholesterol in the blood.

PROPER USE OF THIS MEDICATION:

- Take this medication exactly as your doctor has instructed.
- Take this medicine at the same time every day, at bedtime.
- To reduce the chance of stomach upset, this medication should be taken with a glass of water or low-fat milk, and a low-fat snack such as a banana, low-fat yogurt or crackers.
- DO NOT take with grapefruit juice, hot liquids, spicy foods and/or alcoholic beverages.
- This medicine should be swallowed whole. DO NOT BREAK, CRUSH or CHEW the tablets.

IMPORTANT INFORMATION TO REMEMBER:

- For most patients this medicine causes mild to moderate flushing; a redness, warmth, itching and/or tingling of the skin. In some patients, flushing may be more intense and additional symptoms may include a rapid or pronounced heartbeat, chills, sweating, swelling, or dizziness, and on rare occasions, fainting. Your doctor may advise you to take an uncoated aspirin, ibuprofen (Advil, Motrin IB) or another non-steroidal anti-inflammatory drug (Aleve, Orudis KT) up to 30 minutes before taking this medicine.
- Since this medicine may cause dizziness or light-headedness, avoid sudden changes in posture. Sit or lie down at the first sign of dizziness. DO NOT drive a car, operate dangerous machinery or do jobs that require you to be alert until you know how you are going to react to this medicine.
- You should follow a standard cholesterol-lowering diet while taking this medicine. Your diet is an important part of controlling your condition.
- DO NOT use any prescription or non-prescription medications or vitamins without first talking with your doctor or pharmacist. Some may affect this medicine or aggravate your condition.
- DO NOT take this medicine if you are pregnant as it may cause fetal harm.
- If you experience muscle pain, weakness or tenderness, CONTACT your doctor immediately. These symptoms may be due to a rare but serious muscle disorder.
- If you have more questions about this medicine or about flushing; contact your doctor or pharmacist, or CALL Kos Pharmaceuticals at 1-888-454-7437.

COMMON SIDE EFFECTS:

Other than flushing, common side effects include nausea, vomiting, diarrhea, itching, rash, weakness, cold or flu symptoms, headache, pain and back pain.

MISSED DOSE INSTRUCTIONS:

If you miss a dose, take your usual dose the next evening. DO NOT DOUBLE the next dose. If you stop taking this medication for a week or more, contact your doctor for instructions.