HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use ZETIA safely and effectively. See full prescribing information for ZETIA.

ZETIA® (ezetimibe) Tablets
Initial U.S. Approval: 2002

----------INDICATIONS AND USAGE----------
ZETIA is an inhibitor of intestinal cholesterol (and related phytosterol) absorption indicated as an adjunct to diet to:
- Reduce elevated total-C, LDL-C, Apo B, and non-HDL-C in patients with primary hyperlipidemia, alone or in combination with an HMG-CoA reductase inhibitor (statin) (1.1)
- Reduce elevated total-C, LDL-C, Apo B, and non-HDL-C in patients with mixed hyperlipidemia in combination with fenofibrate (1.1)
- Reduce elevated total-C and LDL-C in patients with homozygous familial hypercholesterolemia (HoFH), in combination with atorvastatin or simvastatin (1.2)
- Reduce elevated sitosterol and campesterol in patients with homozygous sitosterolemia (phytosterolemia) (1.3)

Limitations of Use (1.4)
- The effect of ZETIA on cardiovascular morbidity and mortality has not been determined.
- ZETIA has not been studied in Fredrickson Type I, III, IV, and V dyslipidemias.

---------- DOSAGE AND ADMINISTRATION----------
- One 10-mg tablet once daily, with or without food (2.1)
- Dosing of ZETIA should occur either ≥2 hours before or ≥4 hours after administration of a bile acid sequestrant. (2.3, 7.4)

---------- DOSAGE FORMS AND STRENGTHS ----------
- Tablets: 10 mg (3)

----------CONTRAINDICATIONS ----------
- Statin contraindications apply when ZETIA is used with a statin:
  - Active liver disease, which may include unexplained persistent elevations in hepatic transaminase levels (4, 5.2)
  - Women who are pregnant or may become pregnant (4, 8.1)
  - Nursing mothers (4, 8.3)
- Known hypersensitivity to product components (4, 6.2)

----------WARNINGS AND PRECAUTIONS----------
- ZETIA is not recommended in patients with moderate or severe hepatic impairment. (5.4, 8.7, 12.3)
- Liver enzyme abnormalities and monitoring: Persistent elevations in hepatic transaminase can occur when ZETIA is added to a statin. Therefore, when ZETIA is added to statin therapy, monitor hepatic transaminase levels before and during treatment according to the recommendations for the individual statin used. (5.2)
- Skeletal muscle effects (e.g., myopathy and rhabdomyolysis):
  - Cases of myopathy and rhabdomyolysis have been reported in patients treated with ZETIA coadministered with a statin and with ZETIA administered alone. Risk for skeletal muscle toxicity increases with higher doses of statin, advanced age (>65), hypothyroidism, renal impairment, and depending on the statin used, concomitant use of other drugs. (5.3, 6.2)

---------- ADVERSE REACTIONS----------
- Common adverse reactions in clinical trials:
  - ZETIA coadministered with a statin (incidence ≥2% and greater than statin alone):
    - nasopharyngitis, myalgia, upper respiratory tract infection, arthralgia, and diarrhea (6)
  - ZETIA administered alone (incidence ≥2% and greater than placebo):
    - upper respiratory tract infection, diarrhea, arthralgia, sinusitis, and pain in extremity (6)

To report SUSPECTED ADVERSE REACTIONS, contact Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., at 1-877-888-4231 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------DRUG INTERACTIONS----------
- Cyclosporine: Combination increases exposure of ZETIA and cyclosporine. Cyclosporine concentrations should be monitored in patients taking ZETIA concomitantly. (7.1, 12.3)
- Fenofibrate: Combination increases exposure of ZETIA. If cholelithiasis is suspected in a patient receiving ZETIA and fenofibrate, gallbladder studies are indicated and alternative lipid-lowering therapy should be considered. (6.1, 7.3)
- Fibrates: Coadministration of ZETIA with fibrates other than fenofibrate is not recommended until use in patients is adequately studied. (7.2)
- Cholestyramine: Combination decreases exposure of ZETIA. (2.3, 7.4, 12.3)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 08/2013

FULL PRESCRIBING INFORMATION: CONTENTS*