The US Food and Drug Administration (FDA) warned about using azithromycin antibiotic as it poses a risk for a potentially fatal irregular heart rhythm and recommended a careful screening of patients using this drug.\(^{(1)}\)

Azithromycin, a macrolide-class antibiotic was found to cause abnormal changes in the electrical activity of the heart, that may prolong the QT interval and trigger a rare, associated arrhythmia called torsades de pointes - uncommon and distinctive form of polymorphic ventricular tachycardia (VT) characterized by a gradual change in the amplitude and twisting of the QRS - in people with certain risk factors, according to FDA officials.\(^{(1)}\)

The FDA stated that patients at risk for azithromycin-induced arrhythmia include those who already have a prolonged QT interval, low blood levels of potassium or magnesium, and abnormal slow heart rate, or who take drugs to treat arrhythmias. Elderly patients and patients with cardiac disease also may be more susceptible to the arrhythmogenic effects of the antibiotic.\(^{(2)}\)

The FDA recommends that physicians should consider other treatment options for patients who already are at risk for cardiovascular events and notes that "the potential risk of QT prolongation with azithromycin should be placed in appropriate context when choosing an antibacterial drug."\(^{(3)}\)

References:
A contraindication for concomitant use of repaglinide and clopidogrel has been added to the product monographs. A drug-drug interaction of repaglinide and clopidogrel may lead to a significant decrease in repaglinide exposure and the risk of hypoglycemia. This drug-drug interaction potentially increases the risk of hypoglycemia.

Health Canada has declared that coadministration of repaglinide and clopidogrel may lead to a significant decrease in repaglinide exposure and the risk of hypoglycemia. A contraindication for the coadministration of repaglinide and clopidogrel has been added to the product monographs. This drug-drug interaction potentially increases the risk of hypoglycemia.
The concomitant use of repaglinide and clopidogrel is now contraindicated.

The prescriber information for GLUCONORM® (repaglinide) has been updated. The prescriber information for PLAVIX® (clopidogrel) is currently being updated. The prescriber information for the generic products will be updated.

References:

"Praluent® is approved for use in adjunct to diet and maximally tolerated statin therapy in adult patients."

On July 2015, Praluent® gained the US Food and Drug Administration (FDA) approval for treatment of High LDL Cholesterol in adult patients.

Praluent® is considered the first cholesterol-lowering treatment approved in a new class of drugs known as proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitors. (1)

Praluent® is an antibody that targets a specific protein, called PCSK9. This protein reduces the number of receptors found on the liver that eliminate LDL cholesterol from the blood. By blocking the ability of PCSK9, more receptors will be available to remove LDL cholesterol from the blood, consequently; it will lower the cholesterol level. (2)

Praluent® is approved for use in adjunct to diet, and maximally tolerated statin therapy in adult patients require additional lowering of LDL cholesterol level, such as patients who suffer from heterozygous familial hypercholesterolemia (HeFH) or from atherosclerotic cardiovascular disease such as stroke or heart attack. (2)

This drug is available in two different doses (75 mg and 150 mg). Both doses are available in a single 1 milliliter (mL) injection. It is given in a single-dose by syringe or prefilled pen that patients self-administer every two weeks. (1)

References:

The Coordination Group for Mutual Recognition and Decentralized Procedures Human (CMDh) has agreed upon new measures to minimize the risk of serious side effects, with codeine-containing medicines when used for cough and cold in children. (1)

Codeine for cough and cold in children below 12 years is now contraindicated, and not recommended with compromised respiratory function in children between 12 and 18 years. (2, 3)

Codeine is also contraindicated in women during breastfeeding and patients known to be CYP2D6 ultra-rapid metabolizers. (3)

Since the way codeine is converted into morphine is unpredictable in children below 12 years,
FDA Strengthens NSAID Warning for Heart and Stroke Risks

The US Food and Drug Administration (FDA) strengthened an existing warning that there is an increased heart attack and stroke risk for the use of non-steroidal anti-inflammatory drugs (NSAIDs). (1)

The first boxed warning regarding NSAIDs heart risk was added by the FDA back in 2005 and no modifications were made ever since that date. NSAIDs are used to reduce fever and pain in minor aches like headache, toothache, backaches, cramps...etc. Common over the counter NSAIDs include ibuprofen and naproxen along with other medications. However, over the years many studies revealed the mechanism of NSAIDs heart risk which is possibly attributed to the decreased prostacyclins. (1,2)

The new recommendations issued by the FDA include the following:

- The risk of heart attack and stroke may increase even with the short-term use, and the risk begins within few weeks of NSAIDs intake.
- The risk is correlated with higher doses and longer treatment durations for NSAIDs.
- In general, the risk is greater in patients with history of heart disease. However, patients with no history of any heart conditions might be at risk.
- The new label indicates that there is no enough information whether the risk is higher or lower for one NSAID compared with the others.
- Patients are at increased risk for heart failure with NSAIDs use. (2)

These new recommendations have been issued following a comprehensive review of new safety information including observational studies, a large combined analysis of clinical trials, and other scientific publications. FDA will require drug manufacturers of NSAIDs products to update their labels with these new recommendations issued by the FDA. (1)

References: