Optum Rx®

Atorvaliq® (atorvastatin) – New drug approval

- On February 1, 2023, the FDA approved CMP Pharma's Atorvaliq (atorvastatin) oral suspension. The approved indications include:
    - To reduce the risk of:
        - Myocardial infarction (MI), stroke, revascularization procedures, and angina in adults with multiple risk factors for coronary heart disease (CHD) but without clinically evident CHD
        - MI and stroke in adults with type 2 diabetes mellitus with multiple risk factors for CHD but without clinically evident CHD
        - Non-fatal MI, fatal and non-fatal stroke, revascularization procedures, hospitalization for congestive heart failure, and angina in adults with clinically evident CHD
    - As an adjunct to diet to reduce low-density lipoprotein cholesterol (LDL-C) in:
        - Adults with primary hyperlipidemia
        - Adults and pediatric patients aged 10 years and older with heterozygous familial hypercholesterolemia (HeFH)
    - As an adjunct to other LDL-C lowering therapies, or alone if such treatments are unavailable, to reduce LDL-C in adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH)
    - As an adjunct to diet for the treatment of adults with:
        - Primary dysbetalipoproteinemia
        - Hypertriglyceridemia.

- Atorvaliq is the first oral suspension formulation of atorvastatin. Atorvastatin is also available generically as an oral tablet and carries the same indications as Atorvaliq.

- The effectiveness of Atorvaliq has been established in adequate and well-controlled trials of atorvastatin tablets.

- Atorvaliq is contraindicated in patients with:
    - Acute liver failure or decompensated cirrhosis
    - Hypersensitivity to atorvastatin or any excipients in Atorvaliq.

- Warnings and precautions for Atorvaliq include myopathy and rhabdomyolysis; immune-mediated necrotizing myopathy; hepatic dysfunction; increases in HbA1c and fasting serum glucose levels; and increased risk of hemorrhagic stroke in patients on atorvastatin 80 mg with recent hemorrhagic stroke.

- The most common adverse reactions (≥ 5%) with Atorvaliq use were nasopharyngitis, arthralgia, diarrhea, pain in extremity, and urinary tract infection.

- In adult patients, the recommended starting dose of Atorvaliq is 10 mg to 20 mg orally once daily. The dosage range is 10 mg to 80 mg once daily. Patients who require reduction in LDL-C greater than 45% may be started at 40 mg once daily.

- In pediatric patients 10 years of age and older with HeFH, the recommended starting dosage of Atorvaliq is 10 mg once daily. The dosage range is 10 mg to 20 mg once daily. In pediatric patients 10 years of age and older with HoFH, the recommended starting dosage of Atorvaliq is 10 mg to 20 mg once daily. The dosage range is 10 mg to 80 mg once daily.

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- CMP Pharma’s launch plans for Atorvaliq are pending. Atorvaliq will be available as a 20 mg/5 mL oral suspension.