

Consumer Update

Dec 2021

Ondansetron and risk of myocardial ischemia

EDA performs label update to include the following:

WARNINGS AND PRECAUTIONS

Myocardial Ischemia

Myocardial ischemia has been reported in patients treated with ondansetron. In some cases, predominantly during intravenous administration, the symptoms appeared immediately after administration but resolved with prompt treatment. Coronary artery spasm appears to be the most common underlying cause. Therefore, monitor or advise patients for signs or symptoms of myocardial ischemia after oral administration.

Adverse Reactions

The following clinically significant adverse reactions are described where in the labeling:

Hypersensitivity Reactions.

QT Prolongation.

Serotonin Syndrome.

Myocardial Ischemia.

Masking of Progressive Ileus and Gastric Distension.

Post-Marketing Experience

Myocardial ischemia was reported predominately with intravenous administration.

References: FDA (Click here)