MedWatch Safety Alert RSS Feed

FDA MedWatch Safety Alerts

Fluoroquinolone Antibiotics: Safety Communication - Increased Risk of Ruptures or Tears in the Aorta Blood Vessel in Certain Patients

FDA review found that fluoroquinolone antibiotics can increase the occurrence of rare but serious events of ruptures or tears in the main artery of the body, called the aorta. These tears, called aortic dissections, or ruptures of an aortic aneurysm can lead to dangerous bleeding or even death. They can occur with fluoroquinolones for systemic use given by mouth or through an injection.

Gilenya (fingolimod): Drug Safety Communication - Severe Worsening of Multiple Sclerosis After Stopping the Medicine

FDA is warning that when the multiple sclerosis (MS) medicine Gilenya (fingolimod) is stopped, the disease can become much worse than before the medicine was started or while it was being taken. This MS worsening is rare but can result in permanent disability.

Implanted Pumps: Safety Communication - Use Caution When Selecting Pain Medicine for Intrathecal Administration

The FDA is aware that patients undergoing treatment or management of pain are commonly given pain medicines in the spinal fluid (intrathecal administration) that are not FDA approved for use with the implanted pump.

SGLT2(sodium-glucose cotransporter-2) Inhibitors for Diabetes: Drug Safety Communication - Regarding Rare Occurrences of a Serious Infection of the Genital Area

Requiring a new warning about this risk to be added to the prescribing information of all SGLT2 inhibitors and to the patient Medication Guide.

Temporary Total Artificial Heart Companion 2 Driver System by SynCardia Systems: Letter to Health Care Providers - Risk of Mortality and Stroke

FDA has reviewed the final results from the post-approval study conducted by SynCardia Systems, LLC. for

their Temporary Total Artificial Heart (TAH-t) Companion 2 Driver System (C2 Driver System). These final results indicate a higher mortality rate and higher stroke rate for patients initially supported with the C2 Driver System compared to patients initially supported with the previous generation driver, the Circulatory Support System (CSS) Console.
