Generic Name:
Triamcinolone and moxifloxacin
Trade Name:
No trade names
Company:
Guardian Pharmacy Services
Notes:

FDA is alerting health professionals of adverse events associated with a drug containing triamcinolone (a steroid) and moxifloxacin (anti-infective) compounded by Guardian Pharmacy Services in Dallas. FDA received adverse event reports on April 5 and June 1, 2017, and conducted follow-up concerning at least 43 patients who were administered intravitreal (eye) injections of the drug at the end of a cataract surgery procedure at the PRG Dallas Ambulatory Surgery Center.

The purpose of the injection was to provide postoperative prophylaxis for ocular inflammation and endophthalmitis with the expectation that the patient would not need to use postoperative eye drops.

Over the course of several months, patients developed various symptoms, including vision impairment (blurred or decreased vision), poor night vision, loss of color perception, photophobia (light sensitivity), glare, halos, flashing lights, ocular discomfort, pain, loss of balance, headaches, and/or nausea. A number of the symptoms were not exhibited until at least 1 month postoperatively.

During follow-up examinations, physicians observed that the patients had diminished visual function involving both visual acuity and visual fields. Optical coherence tomography testing initially showed macular edema, which was followed in some cases by retinal degeneration. While the symptoms reportedly improved in some patients over the 5-month postoperative period, a number of patients remain with a significant reduction in best-corrected visual acuity and visual fields.

Medication Monitor Categories:
Alerts and Recalls