



Office of the Ombudsman for Mental Health and Developmental Disabilities



Injectable Medication Alert – RISPERDAL® CONSTA®



This Medical Alert is based on the work of the Medical Review Subcommittee and should be posted prominently. The Office of the Ombudsman for Mental Health and Developmental Disabilities works to improve the services provided to people with disabilities by communicating important information found in the Medical Review Subcommittee's reviews of deaths and serious injuries. Thank you for promptly reporting deaths and serious injuries. You are helping us to meet our mission.

The Medical Review Subcommittee recommended the development of this Medical Alert to remind providers of the need to use the needle provided by the manufacturer when administering Risperdal Consta.

While reviewing the unexpected death of a client, the MRS discussed the prescription of Risperdal Consta and was concerned that it was possible that the client may not have been receiving her injections of Risperdal Consta as ordered. The MRS considered the possibility that if the Risperdal Consta had been administered with any needle other than the needle provided with the medication by the manufacturer that the active medication could remain behind in the syringe, particularly when a smaller gauge needle is used for patient comfort.

Providers can read more about this at

<http://www.risperdalconsta.com/sites/default/files/ipi-download.pdf>

From page 7 -

“RISPERDAL® CONSTA® must be reconstituted **only** in the diluent supplied in the dose pack, and must be administered with **only** the appropriate needle supplied in the dose pack for gluteal (2-inch needle) or deltoid (1-inch needle) administration. All components are required for administration. Do not substitute any components of the dose pack. To assure that the intended dose of risperidone is delivered, the full contents from the vial must be administered. Administration of partial contents may not deliver the intended dose of risperidone.”

From page 8 –

“Upon suspension of the microspheres in the diluent, it is recommended to use RISPERDAL® CONSTA® immediately. If RISPERDAL® CONSTA® is not administered within 2 minutes of reconstitution, settling of the microspheres will occur and resuspension by shaking is necessary prior to administration. Keeping the vial upright, shake vigorously back and forth for as long as it takes to resuspend the microspheres. Once in suspension, the product may remain at room temperature (do not expose to temperatures above 77°F (25°C)). RISPERDAL® CONSTA® must be used within 6 hours of suspension.”

Could this happen to your client?

Suicide of a client under commitment for mental illness. A 53-year-old woman, with paranoid schizophrenia, hypertension, dyslipidemia, and diabetes mellitus type I, died in July 2009 after stepping in front of a semi-trailer truck. Her death was reported to the medical examiner, and an autopsy was done. Her manner of death was suicide, and her immediate cause of death was attributed to basal skull fracture with laceration of the brain, with schizophrenia noted on her death certificate as another significant condition contributing to her death.

History reviewed by this office showed that the client had contact with mental health providers in mid-2008 but denied that she had a mental illness and refused services and medications. She was hospitalized in November and December 2008. During this hospitalization she was committed as mentally ill. Finding a placement was difficult as the client continued to refuse to take medication. She was discharged to a shelter from which she was soon evicted due to her behavior. In early February 2009, she again contacted providers for assistance in locating housing. She had been living with friends as well as in her car. An adult foster care placement was offered, but the client declined. She was then hospitalized due to psychosis, the safety issues related to her poor management of diabetes, and the fact that she was living in a car during the winter. During this hospitalization, providers petitioned the court for authority to administer neuroleptic medication against the client's will. A Jarvis petition was granted, and the client was started on Risperdal Consta injections. The client was hospitalized in a 45 day community hospital contract bed. After 45 days, she was transferred to a state-operated community behavioral health hospital. She remained there until early June 2009. Her psychiatric condition and insight into her illness improved. Throughout her hospitalizations, the client denied suicidal ideation. She reportedly had attempted suicide in the past, date unknown.

She was provisionally discharged to an adult foster care home and was seen twice weekly by an intensive community team. In June, the client's commitment was extended until December 2009. At the time of her death, the client had been prescribed several medications including Risperdal Consta 37.5mg IM every two weeks. She expressed some concerns about her foster care home but did not want to move and did not want staff to assist her in talking to the foster care provider about her concerns. On the day before her death, she acknowledged the possibility that she was experiencing some symptoms of depression. Staff encouraged her to talk with her psychiatrist about this at her upcoming appointment.

On the day that she died, the client told the foster care provider that she was going for a walk at a campground. The client parked her car on the side of an interstate highway and stepped out in front of a semi-tractor trailer. She was pronounced dead at the scene. After her death, witnesses reported that they saw her attempt the same action about one-half mile away, but the truck driver was successful at avoiding her.