WinRho SDF (Rho(D) Immune Globulin Intravenous (Human): Risk of Intravascular Hemolysis

FDA MedWatch

Cangene, Baxter and FDA notified healthcare professionals that cases of intravascular hemolysis (IVH) and its complications, including fatalities, have been reported in patients treated for immune thrombocytopenic purpura (ITP) with WinRho SDF. IVH can lead to clinically compromising anemia and multi-system organ failure including acute respiratory distress syndrome. Serious complications including severe anemia, acute renal insufficiency, renal failure and disseminated intravascular coagulation have also been reported. Fatal outcomes associated with IVH and its complications have occurred most frequently in patients of advanced age (age over 65) with co-morbid conditions.
The Boxed Warning informs healthcare professionals that:

- Patients should be closely monitored in a health care setting for at least eight hours after administration
- A dipstick urinalysis should be performed at baseline, 2 hours, 4 hours after administration and prior to the end of the monitoring period
- Patients should be alerted to and monitor for signs and symptoms of IVH, including back pain, shaking chills, fever, and discolored urine or hematuria. Absence of these signs and/or symptoms of IVH within eight hours do not indicate IVH cannot occur subsequently.
- If signs and/or symptoms of IVH are present or if IVH is suspected after WinRho administration, post-treatment laboratory tests should be performed including plasma hemoglobin, urinalysis, haptoglobin, LDH and plasma bilirubin (direct and indirect).

SOURCE [1]

Links:
[1] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm203739.htm