NATIONAL PBM BULLETIN

JANUARY 22, 2008

DEPARTMENT OF VETERANS AFFAIRS - VETERANS HEALTH ADMINISTRATION
PHARMACY BENEFITS MANAGEMENT SERVICE (PBM), MEDICAL ADVISORY PANEL (MAP), AND
CENTER FOR MEDICATION SAFETY PSCI (VA MEDSAFE)

CHEMOTHERAPY FINAL DOSE CONCENTRATIONS FOR TEMSIROLIMUS (TORISEL™)

I. ISSUE

A concentration error has been reported during the preparation of Torisel™(temsirolimus) injection at one VAMC.

II. BACKGROUND

One VAMC recently had a medication error related to the preparation of Torisel™ (temsirolimus) injection. The product comes as a kit containing two vials: the first vial is the active drug and is labeled as 25 milligrams (mg)/milliliter (ml); the second vial contains 1.8 ml of diluent. The mixing instructions are only found in the package insert and not on the individual vials. To prepare the drug for administration, the diluent is added to the vial of active Torisel™ to yield a volume of 2.5 mL. This diluted solution is then used to draw up the final dose, which is added to 250 ml of 0.9% Sodium Chloride for infusion over 30-60 minutes.

The pharmacy staff involved in preparing the medication did not realize that by adding the diluent to the vial containing active drug, the resulting concentration was now 10 mg/ml instead of 25 mg/ml as marked on the vial of active Torisel™. When the dose was drawn up, only 1 ml (10 mg) was removed instead of 2.5 ml (25 mg). When the pharmacist checked the final product, they compared the amount drawn up (1 ml) with the Torisel™ vial (labeled 25 mg/ml) and concluded that the correct dose had been withdrawn. This resulted in the patient receiving less than the ordered dose (10 mg instead of the intended 25 mg).

The error was discovered by a staff member who correctly prepared the product with 2.5 ml of the final solution and pointed out the instructions in the package insert to the checking pharmacist.

III. VA MEDSAFE RECOMMENDATIONS

1. When preparing temsirolimus (Torisel™) injection, staff must be aware of temsirolimus concentrations before and after dilution.
2. Pharmacy must keep the package insert with the full instructions for dilution of temsirolimus (Torisel™) injection with the vials of both active drug and diluent, since no instructions appear on the vials themselves.
3. Pharmacy must create a warning system to notify staff of the change in concentration when preparing the final dilution of temsirolimus (Torisel™) injection (i.e., computer alerts during the ordering/verifying process and/or warning stickers on packaging).

IV. SOURCE

VISN 2 Safety Alert Report.