IV Compatibility Product

Trissel's Drugs and Solutions Data

Cabazitaxel

Trade Name(s)	JEVTANA
pH Range	pH in aqueous solutions is not provided by the manufacturer.
Formulation [1017]	Provided as a kit containing a clear, viscous yellow to yellow-brown liquid concentrate of cabazitaxel in single-use vials of 60 mg/1.5 mL (40 mg/mL) in polysorbate 80. The vial of concentrate is accompanied by a vial of special diluent composed of ethanol 13% in water for injection. The vials of drug and special diluent contain overfills to compensate for loss during preparation.
Reconstitution [1017]	Cabazitaxel is a drug that should be handled as hazardous. If cabazitaxel should contact the skin, immediately and thoroughly wash the area with soap and water. If the drug should contact mucosa, immediately and thoroughly wash with water. Cabazitaxel is prepared for intravenous infusion in a two-step process under aseptic conditions: (1) Prepare the initial dilution by withdrawing the entire contents of the accompanying vial of special diluent and slowly adding it to the cabazitaxel concentrate by directing the flow from the needle onto the inside wall of the vial to limit foaming. After removing the syringe and needle, the vial should be repeatedly inverted for about 45 seconds to thoroughly mix the solution. Do NOT shake. Allow the vials to stand until most foam has dissipated. This initial dilution is a clear solution having a cabazitaxel concentration of 10 mg/mL that must be diluted for infusion within 30 minutes of initial dilution. (2) The proper dose of cabazitaxel is then withdrawn from the vial of the initial 10-mg/mL dilution and is added to a 250-mL (or larger if necessary) glass, polyethylene, or polypropylene (PVC-free) container of dextrose 5% or sodium chloride 0.9% to result in a final cabazitaxel concentration of 0.1 to 0.26 mg/mL. After removing the syringe and needle, mix thoroughly by inversion of the container.
Storage [1017]	Store intact containers of cabazitaxel at controlled room temperature. Do NOT store under refrigeration.
Maximum Stability [1017]	Maximum reported stability periods: Initial 10-mg/mL dilution- 30 minutes at room temperature. In D5W (non-PVC container)- 8 hours at room temperature and 24 hours refrigerated. In NS (non-PVC container)- 8 hours at room temperature and 24 hours refrigerated. NOTE: Subject to possible precipitation. Precipitation may occur before the maximum times noted.
Stability (Detailed) [1017]	The intact vials of cabazitaxel stored as directed by the manufacturer are stable until the labeled expiration date.

The manufacturer states that the cabazitaxel 10-mg/mL initial dilution prepared in the accompanying special diluent should be diluted further for infusion within 30 minutes after the initial dilution step.

The manufacturer states that cabazitaxel admixtures in dextrose 5% or sodium chloride 0.9% at concentrations between 0.1 and 0.26 mg/mL should be used within 8 hours at room temperature and 24 hours if refrigerated, including the 1-hour administration period. Any unused solution should be discarded.

Cabazitaxel upon initial dilution and diluted for infusion are supersaturated solutions. Cabazitaxel is subject to variable and erratic precipitation from solutions prepared for administration like the related taxane drugs docetaxel and paclitaxel. If the solution is not clear or appears to have a precipitate, it should be discarded.

Factors that may influence the physical stability of cabazitaxel in aqueous solutions are expected to be similar to those influencing paclitaxel precipitation and include drug concentration, type of solution container, infusion solution, storage temperature, formulation pH, and possibly other factors. For the taxane drugs, exact and reliable prediction of long-term physical stability periods of dilutions does not appear to be possible. Because of the irregularity and uncertainty of when or whether precipitation might occur, attention and vigilant observation are needed during administration. In addition, the use of an inline 0.22-micron filter is required by the manufacturer of cabazitaxel (as it is for paclitaxel infusions) because of the potential for precipitation to occur.

Interaction with Plastics [1017]

The manufacturer of cabazitaxel states that the drug should not be administered using polyvinyl chloride (PVC) containers or administration sets or polyurethane infusion sets.

Leaching:

The polysorbate 80 surfactant of the cabazitaxel formulation leaches diethylhexyl phthalate (DEHP) plasticizer from polyvinyl chloride (PVC) containers and administration set tubing. The amount of DEHP that will be leached may vary depending on the surfactant concentration, size of the PVC container, dimensions of the PVC tubing, temperature, and contact time.

A maximum of 5 mcg/mL of leached DEHP has been proposed based on metabolic and toxicologic considerations. Tickner et al. have reviewed the health concerns associated with leached DEHP in patients.

The use of non-PVC equipment such as glass or polyolefin (i.e. polyethylene or polypropylene) containers and polyethylene-lined administration sets to minimize the amount of leached plasticizer are usually recommended for taxane drugs with their high surfactant content.

Filtration [1017] [2047]

The use of an inline 0.22-micron filter is required for administration of cabazitaxel infusions.

Other Information [1017]

The manufacturer states that cabazitaxel should not be mixed with other drugs.

Reference Section