Common Clinical Questions

DIPRIVAN® INJECTABLE EMULSION propofol

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1. Does DIPRIVAN? contain sulfite?

No, it does not. As noted in the prescribing information for DIPRIVAN, propofol is very slightly soluble in water and, thus, is formulated in a white, oil-in-water emulsion. In addition to the active component, propofol, the formulation also contains soybean oil (100 mg/mL), glycerol (22.5 mg/mL), egg lecithin (12 mg/mL); and disodium edetate (0.005%); with sodium hydroxide to adjust pH. The DIPRIVAN emulsion is isotonic and has a pH of 7-8.5.

2. Does DIPRIVAN contain Latex?

The rubber plunger in the syringes and the bung of the vials is an elastomeric formulation of 100% bromobutyl rubber, a synthetic rubber. No form of natural rubber latex is used in the manufacture of these packaging components.

3. What is the phosphorus content of the DIPRIVAN formulation?

The emulsion vehicle used in the formulation of DIPRIVAN contains 15 millimoles of phosphorus (bound in the lipid phase) per liter.

4. What components of the DIPRIVAN formulation contribute to the caloric load?

The emulsion portion of the DIPRIVAN formulation is identical to that found in Intralipid 10% (Clintec Nutrition). In addition to the glycerol and egg lecithin described in the labeling, it contains 10% soybean oil which is composed of a mixture of neutral triglycerides of predominantly unsaturated fatty acids. The major component fatty acids are linoleic (50%), oleic (26%), palmitic (10%), linolenic (9%) and stearic (3.5%). Linoleic acid is an Omega-6 fatty acid, linolenic acid is an Omega-3 fatty acid, and oleic acid is an Omega-9 fatty acid. This formulation contains, on average, 3% w/v cholesterol and provides 1.1 kilocalories and 0.1 g of fat per mL. Triglycerides account for slightly less than 85% of the total calories, while glycerol contributes about 9%, and the phospholipid portion about 7%.

5. **Is it necessary to use the vent spike provided with the DIPRIVAN vial?**

The vent spike is provided as a "value added" item with the 50 mL vial and a stopcock is provided with the 100 mL vial as added value. It is not mandatory that either of these items be used during administration from the vials, but venting of the vial must be achieved through some means to allow proper flow of DIPRIVAN. When DIPRIVAN is administered directly from the vial, the vial rubber stopper should be disinfected using 70% isopropyl alcohol. A sterile giving set or a combination of a vent spike and sterile tubing must be used. Administration should commence promptly and must be completed within 12 hours after the vial has been spiked. The dedicated giving set and any unused portions of DIPRIVAN must be discarded after 12 hours.

6. **How often must the tubing be changed when administering DIPRIVAN?**

Strict aseptic technique must always be maintained during handling. DIPRIVAN injectable emulsion is a single-use parenteral product that contains 0.005% disodium edetate to retard the rate of growth of microorganisms in the event of accidental extrinsic contamination. However, DIPRIVAN injectable emulsion can still support the growth of microorganisms as it is not an antimicrobially preserved product under USP standards. Therefore, time limitations for the administration of DIPRIVAN from any one specific container have been established. These limitations pertain only to the specific components (vial, syringe, tubing, etc.) dedicated solely to the administration of DIPRIVAN. They do not apply to devices or tubing which are in place to facilitate the administration of two or more solutions, including DIPRIVAN, which may then be admixed. When DIPRIVAN is administered directly from the vial, the vial rubber stopper should be disinfected using 70% isopropyl alcohol. A sterile vent spike and sterile tubing must be used. Administration should commence promptly and must be completed within 12 hours after the vial has been spiked. The dedicated tubing and any unused portions of DIPRIVAN must be discarded after 12 hours. If withdrawing DIPRIVAN from a vial with a syringe, the vial rubber stopper should be disinfected using 70% isopropyl alcohol. DIPRIVAN injection should be prepared for SINGLE PATIENT USE ONLY. Administration should begin promptly. Any unused portion of DIPRIVAN, its container, dedicated tubing and/or solutions containing DIPRIVAN must be discarded within 6 hours after withdrawing DIPRIVAN from the vial.

7. **What are the manufacturing specifications of the DIPRIVAN pre-filled syringe, and which infusion devices does it fit?**

In mid-1996, a DIPRIVAN 50 mL pre-filled glass syringe was introduced which is suitable for providing continuous infusion when placed in an appropriate infusion pump. To maximize the number of infusion pump designs in which this syringe would be compatible, the outside barrel diameter was made equal to that of the standard Becton- Dickinson 60 cc syringe.