Cleviprex® (clevidipine) Injectable Emulsion
Dosing and Administration Fact Sheet

Materials Needed

The following items are needed to administer Cleviprex:

- **Vial of Cleviprex** (50-mL or 100-mL)
- **Infusion pump** (either a volumetric infusion pump or syringe pump may be used; the infusion device should allow for calibrated infusion rates)
- **Standard vented IV tubing**
- **BP cuff or arterial line** (to monitor BP continually during Cleviprex infusion)

Before Administration

The following steps should be performed before Cleviprex is administered:

- Maintain strict aseptic technique while handling Cleviprex
- Invert vial gently several times before use to ensure uniformity of the emulsion prior to administration
- Inspect for particulate matter and discoloration before administration (do not use if contamination is suspected)
- Administer Cleviprex using an infusion device allowing calibrated infusion rates
- Cleviprex can be administered by a peripheral line or a central catheter
  - Manual catheter priming, according to hospital policy, should be considered for the administration of Cleviprex
  - Follow your hospital protocol for delivering low-volume infusates
- IV line filters (1.2 microns) may be used, but are not required

IV Compatibility

- Cleviprex should not be administered in the same line as other medications
- Cleviprex has Y-site compatibility with Water for Injection, USP; Sodium Chloride (0.9%) Injection, USP; Dextrose (5%) Injection, USP; Dextrose (5%) in Sodium Chloride (0.9%) Injection, USP; Dextrose (5%) in Ringers Lactate Injection, USP; Lactated Ringers Injection, USP; 10% Amino Acid

Please see back page for Important Safety Information.
Please see accompanying full Prescribing Information.

For Medical Information, please call 888-977-MDCO (6326).
During Administration

- **Monitor BP and heart rate**: BP and heart rate should be monitored continually during infusion, and then until vital signs are stable via BP cuff or arterial line.
- **Initial dose**: 1–2 mg/h (convert to mL/h by multiplying by 2)\(^1\)
- **Titrations**:
  - Titrate dose to desired BP reduction
  - Initially, dose may be doubled at 90-second intervals
  - As BP approaches goal, dose increases should be less than doubling and the time between dose adjustments should be every 5–10 minutes
- **Maintenance dose**: 4–6 mg/h for most patients\(^1\)
- **Maximum dose**:
  - Most patients were treated with maximum doses of 16 mg/h or less\(^1\)
  - Severe hypertension is likely to require higher doses
  - There is limited short-term experience with doses up to 32 mg/hour
  - No more than 1,000 mL, or an average of 21 mg/h, is recommended per 24-hour period (other lipid-containing fluids should be considered when calculating lipid load for individual patients)\(^1\)
    - In a clinical study, no clinically significant changes occurred in serum triglyceride levels in Cleviprex\(^\text{®}\)-treated patients\(^2\)
    - There is little experience with infusions beyond 72 hours at any dose\(^1\)
- **Discarding the vial**:
  - Use aseptic technique to discard any unused product\(^1\)
  - Discard single-use vials within 12 hours of stopper puncture\(^1\)
  - Change tubing per existing policy

Transitioning Off Cleviprex

- **Transitioning to oral therapy with Cleviprex**:
  - Titrate downward or discontinue to achieve desired BP while appropriate oral therapy is established\(^1\)
  - Consider the lag time of onset of the oral agent’s effect\(^1\)
  - Continue BP monitoring until desired effect is achieved\(^1\)
  - In most patients, full recovery of BP is achieved in 5–15 minutes after the infusion is stopped\(^1\)
  - If Cleviprex is discontinued without transition to another agent, monitor for the possibility of rebound hypertension for at least 8 hours after infusion is stopped\(^1\)

Storage

Leave vials in cartons until use. Cleviprex is photosensitive and storage in cartons protects against photodegradation. Protection from light during administration is not required.\(^1\)

Store vials refrigerated at 2°C–8°C (36°F–46°F). Do not freeze. Vials in cartons may be transferred to 25°C (77°F, USP controlled room temperature) for a period not to exceed 2 months. Upon transfer to room temperature, mark vials in cartons: “This product was removed from the refrigerator on __/__/__/ date. It must be used or discarded 2 months after this date or the labeled expiration date (whichever comes first).” Do not return to refrigerated storage after beginning room temperature storage.\(^1\)

Important Safety Information

Cleviprex is contraindicated in patients with:
- Allergies to soybeans, soy products, eggs, or egg products;
- Defective lipid metabolism seen in conditions such as pathologic hyperlipemia, lipid nephrosis, or acute pancreatitis if it is accompanied by hyperlipidemia; and
- Severe aortic stenosis.

Cleviprex is intended for intravenous use. Use aseptic technique and discard any unused product within 12 hours of stopper puncture.

Hypotension and reflex tachycardia are potential consequences of rapid upward titration of Cleviprex. If either occurs, decrease the dose of Cleviprex. There is limited experience with short-duration therapy with beta-blockers as a treatment for Cleviprex-induced tachycardia.

Dihydropyridine calcium channel blockers can produce negative inotropic effects and exacerbate heart failure. Monitor heart failure patients carefully.

Cleviprex gives no protection against the effects of abrupt beta-blocker withdrawal. Beta-blockers should be withdrawn only after a gradual reduction in dose.

Patients who receive prolonged Cleviprex infusions and are not transitioned to other antihypertensive therapies should be monitored for the possibility of rebound hypertension for at least 8 hours after the infusion is stopped.

Cleviprex contains approximately 0.2 g of lipid per mL (2.0 kcal). Lipid intake restrictions may be necessary for patients with significant disorders of lipid metabolism.

There is no information to guide use of Cleviprex in treating hypertension associated with pheochromocytoma.

Most common adverse reactions are (>2%) are headache, nausea, and vomiting.


Please see accompanying full Prescribing Information.

For more information, please call 888-977-MDCO (6326) or visit www.Cleviprex.com.