

Prothrombin Complex Concentrate, human (Kcentra) in SWFI

SUPPLIES *include quantity and medication name, strength/concentration, volume, diluent, diluent volume, and quantity and name of each supply needed*

*****NS flush syringes are never to be used for reconstitution/diluent for medication.*****

- Human Prothrombin Complex Concentrate (Kcentra) kit - quantity per Epic order. Depending on local inventory, each kit consists of:
 - Kcentra 500-unit range single dose vial(s)
 - Dosing based on Factor IX of the actual vial



- Sterile water for injection (SWFI) 20 mL vial(s)
- Mix2Vial transfer set
- Alcohol swab

OR

- Kcentra 1,000- unit range single dose vial(s)
 - Dosing based on Factor IX of the actual vial
- SWFI 40 mL vial(s)
- Mix2Vial transfer set
- Alcohol swab

- One or more (≥ 1) sterile IV syringe(s)
- One (1) empty, sterile IV bag
- Nursing IV admixture label(s) – Lawson # 626

STEPS *explicitly state each step in chronological order, including hand washing, gown/garb, alcohol swab, etc.)*

Single-Patient Nurse Mixing Instruction Sheet

Non-24/7 Pharmacies and Free-Standing Emergency Department

Mix2Vial Transfer Set

1. Ensure KCENTRA and diluent vials are at room temperature.
2. Remove flip caps from the KCENTRA and diluent vials.
3. Wipe the stoppers with the alcohol swab provided and allow to dry prior to opening the Mix2Vial package.



4. Open the Mix2Vial package by peeling off the lid. Do **not** remove the Mix2Vial from the blister package.



5. Place the **diluent vial** on an even, clean surface and hold the vial tight. Take the Mix2Vial together with the blister package and push the spike of the **blue** adapter end **straight down** through the diluent vial stopper.



6. Carefully remove the blister package from the Mix2Vial set by holding at the rim, and pulling **vertically** upwards. Make sure that you only pull away the blister package and not the Mix2Vial set.



7. Place the **KCENTRA vial** on an even and firm surface. Invert the diluent vial with the Mix2Vial set attached and push the spike of the **transparent** adapter end **straight down** through the KCENTRA vial stopper. The diluent will automatically flow into the KCENTRA vial.

Note: If the vacuum in the KCENTRA vial is accidentally lost during reconstitution with the Mix2Vial device, the transfer with the Mix2Vial will not work.

In this case, separate the set into two pieces as illustrated in Fig. 6 below; do not discard the diluent vial. Place the KCENTRA vial aside on a flat surface. Remove the blue adapter end from the diluent vial of the Mix2Vial set (Fig. 5) by lifting and bending the blue adapter to the side until it disconnects from the diluent vial.



Fig. 5



Fig. 6

For reconstitution:

- Using a separate sterile needle and syringe, withdraw the remaining diluent. Remove the needle from the syringe.
- Attach the syringe to the transparent adapter of the KCENTRA vial as illustrated in Fig. 8 below, and transfer the entire diluent volume into the KCENTRA vial. Remove syringe.
- Gently swirl the KCENTRA vial to ensure the product is fully dissolved. Do not shake.
- Proceed to step 10.



Fig. 8



8. With one hand, grasp the KCENTRA-side of the Mix2Vial set, and with the other hand grasp the diluent-side and unscrew the set carefully counterclockwise into two pieces. Discard the diluent vial with the blue Mix2Vial adapter attached.



9. Gently swirl the KCENTRA vial with the transparent adapter attached until the substance is fully dissolved. Do not shake.



10. Draw air into an empty, sterile syringe. While the KCENTRA vial is upright, connect the syringe to the Mix2Vial's Luer Lock fitting by screwing clockwise. Inject air into the KCENTRA vial.



11. While keeping the syringe plunger pressed, turn the system upside down and draw the solution into the syringe by pulling the plunger back slowly.

12. Now that the solution has been transferred into the syringe, firmly hold on to the barrel of the syringe (keeping the syringe plunger facing down) and disconnect the transparent Mix2Vial adapter from the syringe by unscrewing counterclockwise.
13. Attach 18 gauge needle to syringe and inject the content of syringe into the empty, sterile IV bag.
14. Label the Kcentra/SWFI bag with:
 - a. Drug name, strength, and dose (if not apparent by the container)
 - b. Diluent and volume (if not apparent by the container)
 - c. Hang-by date and time (**administration must begin within 1 hour from the time of compounding**)
 - d. Initials of person compounding

NOTES explicitly state (if applicable) any pertinent information

- Protect final product from light. Cover with light protected plastic bag (e.g. brown plastic bag).

References

- Human Prothrombin Complex Concentrate (Kcentra) [prescribing information]. Kankakee, IL: CSL Behring GmbH. Revised 5/2023. <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=eee1afb8-324c-42e4-8bf0-f0c9da5e6d42&type=display>
- United States Pharmacopeia (USP). General Chapter, <797> Pharmaceutical Compounding—Sterile Preparations. (2023) USP-NF. Rockville, MD: United States Pharmacopeia.

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<https://ochsnerhealth.sharepoint.com/sites/ClinicalResources/SiteAssets/Forms/AllItems.aspx?id=%2Fsites%2FClinicalResources%2FSiteAssets%2FSitePages%2FRegulatory%2DReadiness%2FUSP%2D797%2DOfficial%2D11%2E1%2E23%2Epdf&parent=%2Fsites%2FClinicalResources%2FSiteAssets%2FSitePages%2FRegulatory%2DReadiness>