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Can Lenalidomide Be Prepared as a Liquid Formulation?

By: Madison Kearns, Pharm.D.

Introduction: Lenalidomide, known by the brand name of Revlimid®, is an oral thalidomide analogue. It is approved by the Food and Drug Administration (FDA) for the treatment of multiple myeloma, mantle cell lymphoma, follicular lymphoma, marginal zone lymphoma, and transfusion-dependent anemia due to certain forms of myelodysplastic syndrome. Due to the risk of embryo-fetal toxicity, lenalidomide is only available through a restricted distribution program called the Lenalidomide REMS program. It is considered a hazardous medication.

Dosage Form Availability: Lenalidomide is available in 2.5 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 25 mg capsules for oral administration with dosage regimens typically targeting a total daily dose of 10 mg to 25 mg. According to the package insert, capsules should be taken whole with water and not opened, broken, or chewed. However, patients with difficulties swallowing or those with feeding tubes may need to be administered a liquid formulation of this medication. Currently, there is no commercially available lenalidomide suspension, necessitating capsule manipulation to create a liquid. Studies assessing the pharmacokinetics and stability of an extemporaneous lenalidomide suspension are summarized below.

Pharmacokinetic Study: Chen and colleagues conducted a pharmacokinetic study evaluating a suspension prepared from lenalidomide powder. The suspension was processed in a sonicator, where ultrasonic vibrations fragmented the particles to enhance dissolution. Six healthy male subjects were administered a single 25 mg dose of oral lenalidomide suspension. Afterward, pharmacokinetic parameters were measured utilizing blood, urine, semen, and feces samples. Lenalidomide demonstrated high bioavailability (>90%) when administered as a suspension and achieved therapeutic plasma concentrations, with a mean peak concentration of 413 ng/mL. The absorption rate of the suspension was more rapid than the capsule formulation, with peak concentrations occurring within approximately 1 hour (range: 0.5-1.02 hours) after administration in contrast to the reported time to peak for capsules ranging from 0.5–6 hours. No deaths, serious adverse events, or study discontinuations due to adverse events were reported, indicating that administration of a lenalidomide suspension was safe. These findings support the bioavailability of a suspension prepared from dissolved lenalidomide powder; however, additional studies were needed to further evaluate the preparation of a lenalidomide suspension from capsules.

In Vitro Capsule Study: Morita and colleagues assessed the in vitro stability and pharmacokinetics of a lenalidomide suspension prepared from the capsule formulation. Five lenalidomide 5 mg capsules were suspended in hot water

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(55°C/131°F) for 10 minutes and left to stand at room temperature. To assess the stability of the lenalidomide suspension, samples were collected at 0, 12, and 24 hours after preparation. Additionally, the rate of recovery of the suspension was evaluated after passage through 8, 12, 20, and 24 French (Fr) percutaneous endoscopic gastrostomy (PEG) tubes. For the tube passage test and adsorption assessment, each sample was assayed three times. The study found that the lenalidomide remained stable for 24 hours in the prepared suspension, and more than 99% of the drug could be recovered from the suspension. No problems such as tube clogging or drug precipitation were observed during passage of the suspension through the tube. Recovery rates of the drug ranged from 94.5% to 98% relative to pre–tube passage levels, indicating minimal adsorption of lenalidomide to the tube. The authors concluded that the study supports both the stability of a lenalidomide suspension and the feasibility of administration via a PEG tube. However, they noted that a pharmacokinetic study was still needed in patients receiving lenalidomide suspension prepared using the simple suspension method through a PEG tube.

Conclusion: The Network for Collaborative Oncology Development & Advancement (NCODA) group publishes an oral oncolytic crush and suspension directory that cites the study by Morita and colleagues as a feasible method for preparing a lenalidomide suspension. For patients who are unable to swallow capsules, the simple suspension method of dispersing intact 5 mg lenalidomide capsules in hot water could be considered for home use. However, it is critical to provide thorough education to patients and caregivers on the safe handling of lenalidomide. If a suspension is prepared at home, it is recommended that caregivers wear gloves while handling lenalidomide capsules. Accidental spillage of lenalidomide on the body should be immediately washed with soap and water and exposure to mucous membranes (e.g., mouth, nose) or eyes should be immediately flushed with plenty of water. Additionally, patients should consult a pharmacist about proper disposal of the medication.

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How To Determine the Dose for Humate-P® and Vonvendi®

By: Anneliese Harp, Pharm. D.

Background: Humate-P® is a combined antihemophilic factor and von Willebrand Factor (vWF) Complex (Human). It is indicated for both hemophilia A and von Willebrand Disease (vWD). In patients with hemophilia A, Humate-P® is indicated only for adults in the treatment and prevention of bleeding. In patients with vWD, Humate-P® is indicated for both adult and pediatric patients for the treatment of spontaneous and trauma-induced bleeding episodes and the prevention of excessive bleeding during and after surgery. Vonvendi®, a recombinant vWF, is used only for patients with vWD. It is indicated in adults and pediatric patients for the on-demand treatment and control of bleeding episodes as well as the perioperative management of bleeding. It is also indicated in adults only for routine prophylaxis to reduce the frequency of bleeding episodes.

Humate-P® Dosing: Humate-P® dosing for hemophilia A is based upon Factor VIII (FVIII) international units (IU). In general, 1 IU/kg of FVIII increases circulating FVIII by ~2 IU per dL (≈2%). For vWD dosing, the dose is based upon von Willebrand Factor Ristocetin Cofactor (vWF:RCo) IU. The average vWF:RCo to FVIII per vial of Humate-P® is 2.4:1. For bleeding episodes in patients with vWD 40–80 IU vWF:RCo per kg body weight every 8–12 hours is recommended. Each Humate-P® box lists values of IU of vWF:RCo and FVIII. It is important to verify with the prescriber whether the IU for Humate-P® in the Epic order denotes vWF:RCo or Factor VIII IU. Of note, the Epic label for Humate-P® lists the IU of Antihemophilic Factor-VWF (vWF:RCo), so the IU of Factor VIII should be added along with the IU of vWF:RCo to the Administration Instructions of the Humate-P® order.

Vonvendi® Dosing: Vonvendi® dosing is based upon vWF:RCo IU. For minor surgery the recommended preoperative dosing is 25 to 30 IU/kg. For major surgery the recommended preoperative dose is 50 ± 10 IU/kg. Each Vonvendi® box lists the vWF:RCo IU amounts; these amounts must be verified before dispensing the medication.

Examples of dosing Humate-P® and Vonvendi® are provided below.

Humate-P® Vial for Examples 1 and 2:

vWF:RCo: 1050 IU/vial
FVIII: 538 IU/vial

Vonvendi® Vial for Example 3:

vWF:RCo: 645 IU/vial

Example 1 — Humate-P® for Hemophilia A

Scenario: 70 kg patient with hemophilia A, baseline FVIII 5%. Major bleed, target FVIII 100%

Step 1: Determine desired rise: Desired rise = 100% – 5% = 95%

Step 2: Calculate FVIII IU needed: IU = weight (kg) × desired rise (%) × 0.5 IU/kg (correction factor) = 70 kg × 95 × 0.5 IU/kg = 3325 IU FVIII (required dose)

Step 3: Convert to vials (FVIII 538 IU/vial); Vials = 3325 IU/538 IU/vial = 6.18 → round down to 6 vials (Pharmacists may round to ± 10% of the required dose)

FVIII delivered = 6 vials × 538 IU/vial = 3228 IU FVIII (falls within ± 10% of the required dose)

Step 4: Convert to Antihemophilic Factor-VWF IU (1050 IU vWF:RCo/vial)**:** 6 vials x 1050 IU/vial = 6300 IU Antihemophilic Factor-VWF

Example 2 — Humate-P® for vWD Bleeding Episode

Scenario: 60 kg patient with vWD/significant bleeding

Step 1: Calculate vWF IU needed = 60 kg (wt) × 60 IU vWF:RCo/kg = 3600 IU vWF:RCo (required dose)

Step 2: Convert to vials (vWF:RCo 1050 IU/vial); Vials = 3600 IU/1050 IU/vial = 3.43 → round up instead of down to 4 vials or 4200 IU (exceeds ± 10% of the required dose but higher dose is preferable due to significant bleeding; the pharmacist needs to contact provider to adjust order in Epic).

vWF delivered = 4200 IU Antihemophilic Factor-VWF

Example 3 — Vonvendi® for vWD Perioperative Management of Major Surgery

Scenario: 75 kg patient with vWD going to surgery

Step 1: Calculate vWF IU needed; vWF needed = 75 kg × 50 IU/kg = 3750 IU vWF:RCo (required dose)

Step 2: Convert to vials; Vials = 3750 IU/645 IU/vial = 5.81 → round up to 6 vials (within 10% of required dose); vWF delivered = 6 vials × 645 IU/vial = 3870 IU Von Willebrand Factor (Recomb)

Conclusion: When calculating the dose for Humate-P® and Vonvendi®, please refer to the examples in this article along with their corresponding package inserts for guidance. Of note, the Epic files for Humate-P® may be in the process of being updated to accurately reflect the correct IU per indication (e.g., Factor VIII for hemophilia A and vWF:RCo for vWD).

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