

## Kedrab<sup>™</sup> (rabies immune globulin [human]) – New drug approval

- On August 25, 2017, <u>Kedrion Biopharma</u> and <u>Kamada announced</u> the FDA approval of <u>Kedrab</u> (<u>rabies immune globulin [human]</u>), indicated for passive, transient post-exposure prophylaxis of rabies infection, when given immediately after contact with a rabid or possibly rabid animal. Kedrab should be administered concurrently with a full course of rabies vaccine.
  - Do not administer additional (repeat) doses of Kedrab once vaccine treatment has been initiated, since this may interfere with the immune response to the rabies vaccine.
  - Do not administer Kedrab to persons with a history of a complete pre-exposure or postexposure rabies vaccination and confirmed adequate rabies antibody titer.
- Rabies is a life-threatening condition that impacts approximately 40,000 people in the U.S. each year.
- The efficacy of Kedrab was demonstrated in a study of 118 healthy adults. Patients were randomized to Kedrab + rabies vaccine or a comparator human rabies immunoglobulin (HRIG) + rabies vaccine. The efficacy variable was rabies virus neutralizing antibody (RVNA) titer at day 14.
  - Efficacy (RVNA titer ≥ 0.5 IU/mL) was demonstrated in 98.2% of the Kedrab group and 100% of the comparator HRIG group.
- Warnings and precautions of Kedrab include previous rabies vaccination, anaphylactic shock, hypersensitivity, thrombosis, hemolysis, live attenuated virus vaccines, interference with serologic testing, and transmissible infectious agents.
- The most common adverse reactions with Kedrab use were injection site pain, headache, muscle pain, and upper respiratory tract infection.
- The recommended dosage of Kedrab is 20 IU/kg body weight intramuscularly, given at the time of the first vaccine dose.
  - Kedrab should not be mixed with the rabies vaccine or administered in the same syringe with the rabies vaccine.
  - Kedrab should not be administered into the same anatomical site(s) as rabies vaccine.
  - As much of the dose as possible of Kedrab should be infiltrated into and around any detectable bite wounds.
  - Consult the Kedrab drug label for further administration details.
- Kedrion Biopharma and Kamada plan to launch Kedrab in early 2018. Kedrab will be available as single-use vials containing 2 mL or 10 mL of ready-to-use solution with a potency of 150 IU/mL



## optumrx.com

OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at **optum.com**.

All Optum® trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews® is published by the OptumRx Clinical Services Department.

©2017 Optum, Inc. All rights reserved.