

KAMRAB RABIES IMMUNOGLOBULIN

INFORMATION FOR GENERAL PRACTITIONERS

28 October 2019

PURPOSE

To advise that there is a current shortage of Imogam, the registered rabies immunoglobulin (RIg) for rabies post-exposure prophylaxis. Patients will be offered an equivalent but unregistered product, KamRAB.

This fact sheet provides information about KamRAB and explains the risks and benefits.

SUMMARY

- RIg is one component of the post-exposure prophylaxis for people who may have been exposed to rabies virus or other lyssaviruses. RIg is in short supply globally and Australia has exhausted its supply of Imogam, the registered human RIg product.
- An alternative human RIg product, KamRAB has been sourced. This is not registered for use in Australia. It is approved under section 19A of the *Therapeutic Goods Act 1989* until 31 January 2021. Therefore no additional forms are required when this product is administered.
<https://www.tga.gov.au/accessing-medicines-during-medicines-shortage>.
- GPs are asked to report any adverse event to their local public health unit on 1300 066 055, and to note which human RIg product was administered (KamRAB or Imogam).

ADDITIONAL BACKGROUND FOR GPs

Further information about indications and methods of administration of RIg is available from the Australian Immunisation Handbook <https://immunisationhandbook.health.gov.au/vaccine-preventable-diseases/rabies-and-other-lyssaviruses>.

RABIES FACTS

Rabies is a zoonotic disease caused by human exposure to saliva or nerve tissue of an animal infected with rabies virus or other lyssaviruses. Lyssaviruses are single-stranded RNA viruses in the family Rhabdoviridae, genus *Lyssavirus*. There are 12 known species with this genus including the classical rabies virus and other closely related lyssaviruses such as Australian bat lyssavirus (ABLV) and European bat lyssaviruses.

Rabies is transmitted through the saliva of an infected animal and individuals become infected when either bitten or scratched or by being exposed to infected animals' saliva through broken skin, eyes, nose or mouth. Exposures to bat or other animal faeces, urine or blood do not pose a risk of exposure to lyssaviruses, nor does living, playing or walking near bat roosting areas.

THE RISK OF GETTING RABIES

The risk of dying of rabies following a bite from an assumed rabid animal where no treatment is provided is estimated to be 15-80% depending on what part of the body was bitten and the species of animal. Scratches are associated with a lower risk of dying of 2-5%.

The risk that a particular animal that caused the bite or scratch is rabid is unknown except in those cases where the animal can either be tested or quarantined until rabies is excluded. Animal behaviour is an unreliable method of determining whether the animal is rabid or not.

Without the administration of RIg, there is a risk of developing the infection prior to the development of antibodies in response to vaccine. It takes about 14 to 21 days for most people to develop antibodies after vaccination.

Administration of vaccine alone will reduce risk of contracting rabies however this is only a partial risk reduction. The WHO recommends RIg in addition to vaccine for post exposure prophylaxis for all Category III exposures as well as Category II exposures due to bats.

POST-EXPOSURE PROPHYLAXIS

Following potential exposure to rabies or other lyssaviruses, it is extremely important that appropriate treatment commences immediately.

Post-exposure prophylaxis (PEP) for rabies virus and other lyssavirus exposures consists of prompt wound management, vaccine and RIg administration. The appropriate combination of these components depends on the extent of the exposure, the animal source of the exposure, the person's immune status and their previous vaccination history. The Australian Immunisation Handbook provides the recommended schedule for PEP.

There is only one RIg product that is registered for use in Australia, Imogam made by Sanofi Pasteur, but supplies are currently exhausted. Public Health authorities have decided to make KamRAB available as an interim measure until supplies of registered product are re-established. KamRAB should be administered in the same way as the registered product and as specified in the Australian Immunisation Handbook.

KAMRAB

As with other human immunoglobulin preparations, KamRAB is produced from the blood of human donors. There are standard measures to prevent infections resulting from the use of medicinal products prepared from human blood or plasma include selection of donors, screening of individual donations and plasma pools for specific markers of infections and the inclusion of manufacturing steps for the inactivation/removal of viruses. Despite this, when medicinal products prepared from

human blood or plasma are administered, the possibility of transmitting infective agents cannot be totally excluded. This also applies to unknown or emerging viruses and other pathogens.

The manufacturer of KamRAB has indicated that these principals are applied to this product, that is, the product is manufactured from donors in the United States from collection centres approved by the US Food and Drug Administration (FDA), viral testing is performed on donations using FDA approved kits and two steps (pasteurisation and solvent/detergent incubation) have been used during manufacture to reduce the risk of viral contamination. The manufacturer has indicated that testing of donations and plasma pools is in place for the blood borne viruses: HIV, hepatitis A virus, hepatitis B virus, hepatitis C virus and parvovirus.

KamRAB is not registered for use in Australia. The product has not yet undergone a full assessment of safety and efficacy by the TGA in Australia. However, KamRAB is produced under Good Manufacturing Practices (GMP) as certified by the government of the country of origin. In addition, the product is currently undergoing clinical trials to allow registration in the US.

REPORTING ADVERSE EVENTS

Human RIg produced under GMP is not expected to cause serious adverse reactions. Further information is provided in the KamRAB product information.

Adverse reactions should be reported by you to the public health unit that has provided the Rig on 1300 066 055, noting whether it was KamRAB or the registered product, Imogam that was administered to a patient. In addition, the patient can report any adverse event directly to the TGA.

Information on reporting adverse events is available from the TGA website (<http://www.tga.gov.au/safety/problem.htm#medicine>).