KAMRAB RABIES IMMUNOGLOBULIN

INFORMATION FOR PATIENTS AND FAMILIES

28 October 2019

SUMMARY

- If you have been potentially exposed to rabies or Australian bat lyssavirus (ABLV), post-exposure treatment is required as soon as possible to prevent you from getting rabies.
- You will require a series of rabies vaccines, and your doctor will assess whether you require an injection of rabies immunoglobulin (RIg) in addition to vaccine.
- RIg is in short supply globally and Australia's supplies of the registered product have been exhausted. An alternative product, KamRAB, which is currently not registered for use in Australia, is being offered to people who need it. It is being made available under section 19A of the Therapeutic Goods Act 1989 https://www.tga.gov.au/accessing-medicines-during-medicines-shortage.
- See your doctor if you feel unwell or notice any adverse reaction following the administration of KamRAB.

WHAT IS RABIES AND WHAT ARE THE SYMPTOMS?

Rabies virus and ABLV belong to a group of viruses called lyssaviruses. All lyssaviruses cause a similar illness known as rabies, which affects the central nervous system and is usually fatal.

People who come into contact with bats in Australia or anywhere overseas, and people who come into contact with wild or domestic land dwelling mammals (especially dogs, cats and monkeys) in a country where there is a rabies virus risk, are at increased risk of rabies.

If potentially exposed to rabies or ABLV, it is extremely important that appropriate treatment commences immediately. Incorrect or incomplete treatment may not prevent infection.

WHY DO I NEED RIG?

RIg is one component of the post-exposure treatment for rabies. Your doctor assesses whether you require RIg in addition to vaccine based on your vaccination history, your medical history and the type of exposure.

RIg will provide short term protection while your body produces its own protective antibodies in response to rabies vaccine. Further information about the administration of RIg, and who may need it is available from the Australian Immunisation Handbook https://immunisationhandbook.health.gov.au/vaccine-preventable-diseases/rabies-and-other-lyssaviruses.

WHAT IS RIG?

Human RIg contains antibodies to rabies. It is prepared from blood that has been donated by people who have previously been vaccinated for rabies.

There is only one RIg product that is registered for use in Australia, and supplies of the product are currently exhausted. Public Health authorities have decided to make KamRAB available as an interim measure, until supplies of registered product are re-established.

HOW DOES KAMRAB DIFFER FROM OTHER HUMAN RIG PRODUCTS?

KamRAB and the registered product that is normally available in Australia are both produced from the blood of human donors. As KamRAB is not registered for use in Australia the product has not yet undergone a full assessment of safety and efficacy by the Therapeutic Goods Administration (TGA) in Australia. KamRAB is being made available under section 19A of the *Therapeutic Goods Act* 1989 https://www.tga.gov.au/accessing-medicines-during-medicines-shortage.

KamRAB is produced under Good Manufacturing Practices (GMP) as certified by the government of the country of origin. Screening processes for blood borne infections are those used in the United States.

WHAT HAPPENS IF I REFUSE TREATMENT WITH KAMRAB?

If you refuse KamRAB, there is a risk that you could develop the infection prior to the development of your own antibodies in response to vaccine. It takes about 14 to 21 days for most people to develop their own antibodies. It is for this reason that the World Health Organization recommends RIg in addition to vaccine for certain exposures and patients.

WHAT ARE THE RISKS?

The risk of contracting rabies varies with the type of animal, the type of exposure (bite or scratch). If a person who was exposed becomes infected with rabies, the disease is almost always fatal.

Blood products carry a small risk of transmitting blood borne infections such as hepatitis C. The manufacturer has indicated that 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 2 steps (pasteurisation and solvent/detergent incubation) have been used during manufacture to reduce the risk of viral contamination.

As with all medicines, there is a small chance that you will have an adverse reaction (or side effect) to KamRAB, such as swelling, pain at the site of injection, or an allergic reaction. See your doctor if you are concerned about any possible adverse event. Adverse events following immunisation can be reported to your local public health unit on 1300 066 055.