Public Health England

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28 August 2014

Dear Colleague

Re: Rabies vaccine and immunoglobulin (SRCN0022)

Based on our risk assessment we recommend that your patient receives a course of post-exposure rabies vaccination with rabies immunoglobulin (RIG). Information on rabies vaccine and RIG can be found in the green book "Immunisation against Infectious Disease" (https://www.gov.uk/government/publications/rabies-the-green-book-chapter-27). This letter provides additional information on the correct administration of rabies vaccine and RIG and should remain with the product.

Rabies immunoglobulin (RIG)

Dosage and volume of RIG

The recommended dose of RIG is 20 IU/kg, and the volume needed to administer this dose needs to be calculated. RIG batches from the same manufacturer do vary in potency. It is therefore **critical** to know the weight of the patient and the potency of the RIG.

The volume required for your patient should have already been provided to you. If not, the description of the potency is indicated in the accompanying letter from BPL and is 100 IU/ml

Administration of RIG

RIG should be infiltrated into the depth of the wound and around the site of the wound if possible. If this is difficult, or the wound has completely healed then RIG can be given in the anterolateral thigh. Where more than 3mls is to be given to young children or more than 5mls to older children and adults the immunoglobulin should be divided and given at different sites.

Vaccine and RIG must never be given at the same anatomical site, but can be given on the same day. RIG is not given after seven days post initiation of rabies PEP vaccine (or to an individual who is already partially immunised).

The RIG used in this country is sourced from overseas human donors following rabies vaccination, and is not from UK donors.

Rabies vaccine

Dose and schedule of vaccine

The recommended UK schedule for unimmunised individuals is 1.0 ml vaccine (1 complete vial) at the following intervals: 0, 3, 7, 14, 28-30, with day 0 being the day of first vaccine administration (this is NOT necessarily the day of the exposure).

If a dose of vaccine is missed, or timing has been compromised, the next vaccine should be given as soon as possible, and considered as the missed dose, and subsequent intervals readjusted. The first three doses of vaccine can be given plus/minus 1 day of the scheduled date if vaccination on the scheduled date is not possible (and to allow for administration that would be on a Saturday or Sunday). The 5th final dose of rabies vaccine should not be given before day 26.

Administration of vaccine

The vaccine should be administered intramuscularly in the deltoid muscle, with each sequential dose given in alternate arms. We recommend that you start in the non-dominant arm. Advice on vaccination of individuals with bleeding disorders can be found in the Green Book page 27.

Storage of vaccine and RIG

The supplied RIG and vaccine should be stored within the cold chain until use, and should be used as soon as possible after receipt.

If you have any further questions about using rabies vaccine or RIG for your patient that are not covered here or in the green book please contact the Rabies Office at Colindale on 0208 327 6204.

Please note the advice given is based on the available information. It remains the responsibility of registered healthcare professionals prescribing, supplying or administering medicines to check the medicine is appropriate for the patient. This includes checking doses, contraindications and drug interactions. The clinician should be aware of potential side effects and communicate these to the patient.

Yours faithfully

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Bio Products Laboratory

27th August 2014

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Dear Doctor/Healthcare Professional,

Re: Human Rabies Immunoglobulin: batch SRCN0022

The Patient Information Leaflet for this product states a potency of 'not less than 150 IU/mL solution for injection'.

During routine testing of the above batch of HRIG, the potency was found to have decreased to 100 IU/mL, which is less than the labelled potency used to calculate dosing.

To assist users, please note:

- To calculate the required dose of HRIG, the potency should be taken as 100 IU/ml
- The volume in the vial is 3.8ml

Hence for a 90kg individual requiring an HRIG dose of 20 IU/kg (i.e. 1800 IU of HRIG) the dose to be administered is 18.0 ml.

BPL will continue to monitor the potency of this batch and any further changes will be communicated to you.

If you have any questions, please contact myself or a member of the BPL Medical Department.

Yours sincerely,

Dr Tim Aldwinckle,
Medical Director,
Bio Products Laboratory Limited

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