

410 Thames Valley Park Drive Reading, Berkshire RG6 1PT United Kingdom

April 2020

Important information for healthcare professionals regarding administration of VERORAB (Rabies Vaccine, Inactivated)

Dear Healthcare Professional,

Due to a shortage of our UK licensed Rabies Vaccine BP (PL 46602/0004), the MHRA has granted approval for Sanofi Pasteur to import and supply our alternative inactivated Rabies Vaccine, VERORAB (not currently licensed in the UK). Sanofi Pasteur would like to provide you with updated guidance on the reconstitution and administration of VERORAB.

According to the Prescribing Information, VERORAB must be administered by the intramuscular route. Good medical vaccination practices (national and international immunisation guidelines), provide recommendations on the length of the needle for intramuscular administration based on patient age and weight^{1,2,3}.

The VERORAB package contains a vial of lyophilized vaccine and a pre-filled syringe with a fixed needle of 0.63 inch (or 16 mm) length that contains 0.5mL of diluent. The supplied prefilled syringe with fixed needle should be used only for vaccine reconstitution. Once the vaccine is reconstituted, a new sterile syringe and needle, which are not contained in the VERORAB package, must be used to withdraw the reconstituted vaccine and administer the vaccine to the patient. The length of the needle used for intramuscular vaccine administration should be adapted to the age and weight of the patient in alignment with the good vaccination practices.

An update of the prescribing information to clarify these instructions will be submitted shortly to the Health Authorities in the countries where VERORAB is licensed and will be subsequently introduced into the product labelling.

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¹ <u>https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.html</u>

² <u>WHO : expert consultation on rabies, third report 2018;</u> TRS 1012 <u>https://apps.who.int/iris/bitstream/handle/10665/272364/9789241210218-eng.pdf</u>

³ Zuckerman JN. BMJ. 2000 Nov 18;321(7271):1237-8; The importance of injecting vaccines into muscle. Different patients need different needle sizes.



If you have any questions relating to this information, please contact the Sanofi Pasteur Medical Information Department on 0845 372 7101.

Please report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card Scheme. It is easiest and quickest to report ADRs online via the Yellow Cards website -<u>https://yellowcard.mhra.gov.uk/</u> or via the Yellow Card app available from the Apple App Store or Google Play Store. When reporting a suspected ADR to a vaccine, please provide the brand name (or product licence number and manufacturer), and the specific batch-number. Adverse events should also be reported to Sanofi Pasteur telephone number 0800 0902314.

Yours faithfully,

lan GRAY Head of Medical Sanofi Pasteur

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