16th June 2020

Inactivated Rabies Vaccine, VERORAB®, updated information on reconstitution and administration

Dear Healthcare professional,

Sanofi Pasteur in agreement with the Malta Medicines Authority would like to inform you of the following:

Summary

• Sanofi Pasteur would like to provide you with clarifications on the instructions for intramuscular administration of VERORAB® (Rabies Vaccine, Inactivated).

• The prefilled syringe with fixed needle supplied within VERORAB 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.

Background on the safety concern

VERORAB® is indicated for the prevention of rabies in children and adults. It can be used before and after exposure to the rabies virus, as a primary vaccination or as a booster.

According to the Prescribing Information, VERORAB must be administered by the intramuscular route. [1,2,3] Good medical vaccination practices (national or international recommendations), provide recommendations on the length of the needle based on patient age and weight to administer the vaccine with intramuscular route.

The VERORAB package contains a vial of lyophilized vaccine and a pre-filled syringe with a fixed needle of 5/8 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.

[1] https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.html
[2] WHO : expert consultation on rabies, third report 2018; TRS 1012 https://apps.who.int/iris/bitstream/handle/10665/272364/9789241210218-eng.pdf
[3] Zuckerman JN. BMJ. 2000 Nov 18;321(7271):1237-8; The importance of injecting vaccines into muscle. Different patients need different needle sizes.

Recommended Needle Size, Length, and Angle for Administering Vaccines

Injection Type	Age	Needle Type	Injection Site	Angle of Needle Insertion
Intramuscular (IM)	Newborns (1st 28 days)	16 mm (5/8 inch) in length and 22-25 G	Anterolateral thigh muscle	90° to skin plane
	Infants (1-12 Months)	25 mm (1 inch) in length and 22-25 G	Anterolateral thigh muscle	
	Toddlers and children (12 - 36 Months)	25-32 mm (1-1¼ inch) in length and 22-25 G	Anterolateral thigh muscle	
	Children >36 months and young adult	25-32 mm (1-1¼ inch) in length and 22-25 G	Deltoid muscle of arm	

An update of the prescribing information to clarify these instructions is currently under evaluation in EU.

Call for reporting

Healthcare professionals are encouraged to report all the adverse events suspected to be associated with VERORAB vaccination to the Malta Medicines Authority. Report Form can be downloaded from http://www.medicinesauthority.gov.mt/adrportal and sent to Post-licensing Directorate, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 Malta, or by e-mail to postlicensing.medicinesauthority@gov.mt

Company contact point

If you have any questions or require additional information, please write to
Sanofi Medical Information at Informazioni.medicoscientifiche@sanofi.com
OR to Sanofi Pharmacovigilance at PharmacovigilanceMalta@sanofi.com

Yours Sincerely

Sanofi Pasteur