SANOFI PASTEUR

Direct healthcare-professional communication (DHPC)

Updated information on the reconstitution and administration of rabies vaccine, inactivated (VERORAB)

19th of July 2020

Dear Healthcare professional,

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

Summary

Method of administration**:** according to the Saudi leaflet, the vaccine is administrated by the intramuscular route, generally in the anterolateral region of the thigh muscle until the age of 12 moths and in the deltoid muscle after this age.

If the Zagreb regimen is used, one dose should be administered in each deltoid muscle (left and right) in adults at D0, then one dose at D7and D21.

Verorab must not be injected in the buttocks' region. The vaccine must not be injected via the intravascular route.

When the intramuscular route is chosen, good medical vaccination practices (national or international recommendations), provide recommendations on the length of the needle based on patient age and weight.

Further information

As CDC recommendation, the needle gauge for intramuscular injection is 22-25 gauge.[2] A decision on needle length and site of injection must be made for each person on the basis of the size of the muscle, the thickness of adipose tissue at the injection site, the volume of the material to be administered, injection technique, and the depth below the muscle surface into which the material is to be injected. [2]

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 <u>only</u> for vaccine reconstitution**. Once the vaccine is

reconstituted, a new sterile syringe and needle, **which is 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.

A statement indicating that the information is being sent in agreement with the SFDA.

If you have any further questions on the use of this medicine, please ask your doctor, pharmacist, or nurse.

Call for reporting

Healthcare professionals are encouraged to report adverse events in patients treated with Lemtrada to National Pharmacovigilance and Drug Safety Center in SFDA.

Website: https://ade.sfda.gov.sa/

E-mail: npc.drug@sfda.gov.sa

Call center: 19999

Fax: +966-11-2057662

Company contact point

Should you have any question or require additional information, please call Medical Information at +966-12-6693318, or contact them via email: ksa.medicalinformation@sanofi.com.

For SANOFI Saudi Arabia Pharmacovigilance Center please contact us in the below contact information.

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Mail: Ksa_pharmacovigilance@sanofi.com

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Kind regards,

Mossab Shafy, *Pharm.D, M.Sc., MBA*

Qualified Person for Pharmacovigilance (QPPV)

Mossab Shafy

Digitally signed by Mossab Shafy
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