**Prescribing Information: Rabies Vaccine BP ≥2.5 IU/ml, Powder and solvent for suspension for injection**
**Please refer to the Summary of Product Characteristics (SPC) before prescribing.**

**Presentation:** A single dose vial of powdered vaccine and pre-filled syringe of solvent for suspension for injection. After reconstitution, each 1 millilitre dose contains rabies virus (inactivated, strain PM/WI 38 1503-3M) not less than 2.5 International Units of rabies antigen.
**Indication:** Rabies Vaccine BP is indicated for pre-exposure prophylaxis and for post-exposure prophylaxis against rabies in all age groups. The use of Rabies Vaccine BP should be based on official recommendations.
**Dosage and Administration:** The recommended dose is 1mL of reconstituted vaccine. The vaccine is for intramuscular administration only. The vaccine should be administered into the deltoid muscle for adults and children or the anterolateral area of the thigh muscle in infants and toddlers.
*Dosage and Pre-Exposure Prophylaxis*: The primary dose pre-exposure immunisation course consists of 3 injections at D0, D7, and either D21 or D28. For individuals at continued risk, booster doses should be given in line with official recommendations.
*Dosage For Post-Exposure Prophylaxis*: Post-exposure prophylaxis should be initiated as soon as possible after suspected exposure. Proper woundcare must be applied immediately or as soon as possible after exposure.
*Post-exposure prophylaxis of previously non-immunised individuals*. Vaccine should be administered on D0, D3, D7, D14 and D28 (5 injections of 1mL).
Previously immunised individuals should receive one dose of vaccine on both days 0 and 3. Rabies immunoglobulin is not indicated in such cases.
*Special population – immunocompromised individuals: Pre-exposure prophylaxis*: For immunocompromised individuals, serology testing of neutralizing antibodies should be performed 2 to 4 weeks after the vaccination to assess the possible need for an additional dose of the vaccine.
*Post-exposure prophylaxis*: For immunocompromised individuals, only a full vaccination schedule should be administered. Rabies immunoglobulin should be given in accordance with local official recommendations.
Paediatric individuals should receive the same dose as adults (1mL).
**Contraindications**: Pre-exposure: Known systemic hypersensitivity to Rabies Vaccine BP or any of its components; febrile and/or acute disease. Post-exposure: no contra-indications.
**Precautions and Warnings**: As with any vaccine, vaccination with Rabies Vaccine BP may not protect 100% of vaccinated individuals. Appropriate facilities and medicines should be readily available in case of anaphylaxis or hypersensitivity following injection. The vaccine may contain traces of neomycin and betapropiolactone which are used during the manufacturing process. If Rabies Immunoglobulin is indicated in addition to Rabies Vaccine BP, then it must be administered at a different anatomical site to the vaccination site.
Rabies Vaccine BP should not be administered to patients with bleeding disorders or to persons on anticoagulant therapy unless the potential benefit outweighs the risk of administration. The tip caps of the pre-filled syringes contain a natural rubber latex derivative, which may cause severe allergic reactions in latex sensitive individuals. The potential risk of apnoea and the need for respiratory monitoring for 48-72 h should be considered when administering the primary immunisation series to very premature infants (born ≤ 28 weeks of gestation) and particularly for those with a previous history of respiratory immaturity.
***Interactions:*** Immunosuppressive treatments, including long-term systemic corticosteroid therapy, may interfere with antibody production and cause the failure of the vaccination. Official recommendations should be followed with regard to co-administration with other vaccines or drugs.
*Fertility, pregnancy and lactation:* Data on limited number of exposed pregnancies do not allow a conclusion on the potential risk of Rabies HDCV for pregnancy or for the health of the foetus/newborn child. Due to the severity of the disease, breast feeding is not considered a contraindication and treatment must not be discontinued.
**Adverse Reactions**:
Very common: injection site pain, malaise, headache, and myalgia
Common: nausea, injection site reactions (erythema, swelling/induration, pruritus, bruising/haematoma), fever, fatigue/asthenia
Other undesirable effects have been reported, although their frequency is uncommon, rare or not known. These include: serum sickness type reaction, anaphylactic reactions, encephalitis, convulsion, neuropathy, and angioedema. For a complete list of undesirable effects please refer to the Summary of Product Characteristics.
**List price:** One single dose vial (powder) and one pre-filled disposable syringe containing 1 millilitre of solvent with up to 2 separate needles, basic NHS cost £40.84.
**Legal Category:** POM
M**arketing Authorisation Number**: PL 46602/0004
**Marketing Authorisation Holder:** Sanofi Pasteur Europe, 14 Espace Henri Vallée, 69007 Lyon, France
**Further information is available from:** Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire RG6 1PT
**Date of preparation:** June 2020

Adverse events should be reported. Reporting forms and information can be found at yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store.

Adverse events should also be reported to the Sanofi drug safety department on Tel: 0800 0902 314. Alternatively, send via email to UK-drugsafety@sanofi.com