Prescribing Information: REPEVAX® Suspension for injection in pre-filled syringe (Diphtheria, Tetanus, Pertussis (acellular, component) and Poliomyelitis (inactivated) Vaccine (adsorbed, reduced antigen(s) content))

Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

Presentation: Available as 0.5 mL single dose of vaccine supplied in pre-filled syringe. Each dose of vaccine contains ≥2 IU Diphtheria Toxoid, ≥20 IU Tetanus Toxoid, 2.5 µg Pertussis Toxoid, 5 µg Filamentous Haemagglutinin, 5 µg Fimbriae Types 2 and 3, 3 µg Pertactin, 29 D antigen units of inactivated type 1 (Mahoney) poliovirus, 7 D antigen units of inactivated type 2 (MEF1) poliovirus, 26 D antigen units of inactivated type 3 (Saukett) poliovirus and 1.5 mg of aluminium phosphate as adjuvant.

Indication: Active immunisation against diphtheria, tetanus, pertussis and poliomyelitis in persons from the age of 3 years as a booster following primary immunisation. Passive protection against pertussis in early infancy following maternal immunisation during pregnancy. REPEVAX should be used in accordance with official recommendations.

Dosage and Administration: All indicated age groups should receive one 0.5 mL dose. The vaccine should be administered by the intramuscular (IM) route, the preferred site is into the deltoid muscle. REPEVAX should not be administered into the gluteal area. Do not administer by intravascular or intradermal injection. Subcutaneous (SC) routes should not be used unless in exceptional cases. In adolescents and adults with an unknown or incomplete diphtheria or tetanus vaccination status, one dose of REPEVAX can be administered as part of a vaccination series to protect against pertussis and poliomyelitis, and in most cases also against tetanus and diphtheria. The number and schedule of doses should be determined according to local recommendations. Physicians should consult the SmPC for more information. REPEVAX can be used for repeat vaccination to boost immunity to diphtheria, tetanus and pertussis at 5 – 10 year intervals. REPEVAX can be used in the management of tetanus prone injuries with or without concomitant administration of Tetanus Immunoglobulin according to official recommendations. REPEVAX may be administered to pregnant women during the second or third trimester to provide passive protection of infants against pertussis.

Contraindications: REPEVAX should not be administered to individuals with known hypersensitivity to diphtheria, tetanus, pertussis or poliomyelitis vaccines, to any residual substances carried over from manufacture (formaldehyde, glutaraldehyde, streptomycin, neomycin, polymyxin B and bovine serum albumin) or to any other component of the vaccine (phenoxyethanol, polysorbate 80, ethanol and adjuvant). REPEVAX should not be administered to persons who experienced an encephalopathy of unknown origin within 7 days of previous immunisation with a pertussis-containing vaccine. As with other vaccines, administration of REPEVAX should be postponed in persons suffering from an acute severe febrile illness. The presence of a minor infection (e.g. mild upper respiratory infection) is not a contraindication.

Warnings and Precautions: REPEVAX should not be used for primary immunisation. Prior to immunisation: Vaccination should be preceded by a review of the person's medical history (in particular previous vaccinations and possible adverse events). In persons who have a history of serious or severe reaction within 48 hours of a previous injection with a vaccine containing similar components, administration of REPEVAX vaccine must be carefully considered. As with all injectable vaccines, appropriate medical treatment and supervision should be readily available in the rare event of anaphylactic reaction. If Guillain-Barré syndrome has occurred within 6 weeks of receipt of prior vaccine containing tetanus toxoid, the decision to give any vaccine containing tetanus toxoid, including REPEVAX, should be based on careful consideration of the potential benefits and possible risks. Immunogenicity of the vaccine may be reduced by immunosuppressive treatment or immunodeficiency. It is recommended to postpone the vaccination until the end of such disease or treatment if practical. Nevertheless, vaccination of HIV infected persons or persons with chronic immunodeficiency, such as AIDS, is recommended even if the antibody response might be limited. REPEVAX should not be administered to persons with a progressive or unstable neurological disorder, uncontrolled epilepsy or progressive encephalopathy until a treatment regimen has been established and the condition has been stabilized. Administration precautions: IM injections should be given with care in patients on anticoagulant therapy or suffering from coagulation disorders because of the risk of haemorrhage. In these situations, and following official recommendations, the administration of REPEVAX by deep SC injection may be considered, although there is a risk of increased local reactions. A persistent nodule at the site of injection may occur with all adsorbed vaccines, particularly if administered into the superficial layers of the subcutaneous tissue. Syncope (fainting) can occur following, or even before, administration of injectable vaccines, including REPEVAX. Procedures should be in place to prevent falling injury and manage syncopal reactions. Excipients of known effect: REPEVAX contains 1.01 mg of alcohol (ethanol) in each 0.5 mL dose. The small amount of alcohol in this medicine will not have any noticeable effects. Polysorbate 80 (E 433) This medicine contains ≤ 5 µg of polysorbate 80 in each 0.5 mL pre-filled syringe, which is equivalent to 10 µg/mL. Polysorbates may cause allergic reactions.

Interactions: REPEVAX may be administered concomitantly with a dose of inactivated influenza vaccine, based on the results of a clinical trial conducted in persons 60 years of age and older. It may also be administered concomitantly with a dose of hepatitis B vaccine. Based on the results of concomitant use clinical studies, REPEVAX can be administered with human papilloma virus vaccine (HPV) and/or Meningococcal Polysaccharide (Serogroups A, C, Y, and W) (MenACYW) conjugate vaccines (either all three vaccines concomitantly or in pairs) according to local recommendations. Separate limbs must be used for the site of injection. Interaction studies have not been carried out with other vaccines, biological products or therapeutic medications. However, in accordance with commonly accepted immunization guidelines, since REPEVAX is an inactivated product, it may be administered concomitantly

with other vaccines or immunoglobulins at separate injection sites.

Fertility, pregnancy and lactation: REPEVAX can be used during the second or third trimester of pregnancy in accordance with official recommendations. As with other inactivated vaccines, it is not expected that vaccination with REPEVAX during any trimester would harm the foetus. See SmPC for information on immune responses to vaccination during pregnancy and its effectiveness at preventing pertussis in infants. The effect of administration of REPEVAX during lactation has not been assessed. Nevertheless, as REPEVAX contains toxoids or inactivated antigens, no risk to the breastfed infant should be expected. The benefits versus the risk of administering REPEVAX to breast-feeding women should be evaluated by the healthcare providers.

Adverse Reactions: Very common: *Adults and adolescents (>6 years):* headache, nausea, arthralgia/joint swelling, myalgia, fatigue/asthenia and chills, injection site reactions (pain, swelling and erythema). *Paediatric population (3 – 6 years):* diarrhoea, fatigue/asthenia and fever, injection site reactions (pain, swelling and erythema). Common: *Adults and adolescents (>6 years):* diarrhoea, vomiting and fever. *Paediatric population (3 – 6 years):* headache, vomiting, nausea, rash, arthralgia/joint swelling, irritability, injection site reactions (dermatitis, bruising and pruritus). Other Serious Adverse Drug reactions (frequency not known): lymphadenopathy, anaphylactic reactions (such as urticaria, face oedema and dyspnoea), extensive limb swelling, injection site induration, transient paraesthesia/hypoesthesia of vaccinated limb, convulsions, vasovagal syncope, facial palsy, myelitis, brachial neuritis and Guillain-Barré syndrome. *Prescribers should consult the SmPC in relation to other adverse reactions.*

List price: Single pack (1 pre-filled syringe): £20.00.

Legal Category: POM

Marketing Authorisation Number: PL 23228/0009

Marketing Authorisation Holder: Sanofi Winthrop Industrie, 82 avenue Raspail, 94250 Gentilly, France.

Further information is available from: Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK. uk-medicalinformation@sanofi.com

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard 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