Prescribing Information: REVAXIS suspension for injection in pre-filled syringe (Diphtheria, Tetanus 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 a pre-filled syringe. Each dose of vaccine contains ≥2 IU of purified diphtheria toxoid, ≥20 IU of purified tetanus toxoid, 29D antigen units of inactivated type 1 poliomyelitis virus, 7D antigen units of inactivated type 2 poliomyelitis virus, 26D antigen units of inactivated type 3 poliomyelitis virus and 0.35 mg of aluminium hydroxide as adsorbant.

Indication: REVAXIS (Td-IPV) is indicated for active immunisation against diphtheria, tetanus and poliomyelitis in adults, adolescents and children from 6 years of age, as a booster following primary vaccination. REVAXIS is not intended for primary immunisation.

Dosage and Administration: Adults, adolescents and children from 6 years of age should receive one 0.5 mL dose. REVAXIS should be administered in accordance with official recommendations and/or local practice. REVAXIS may be used as a booster following primary immunisation with inactivated or oral poliomyelitis vaccines (IPV or OPV). There are no clinical data available regarding the use of REVAXIS in individuals with an incomplete, or no, history of a primary series of diphtheria and tetanus toxoids or of vaccinations against poliomyelitis. Although REVAXIS has not been studied in subjects with tetanus-prone injuries, studies have shown that it induces similar tetanus antitoxin titres to Td vaccine. Therefore, it may be used in subjects with tetanus-prone injuries if concomitant vaccination against diphtheria and poliomyelitis is desirable. The vaccine should be administered by the intramuscular (IM) route. REVAXIS must not be administered by intradermal or intravascular routes. Under certain conditions (e.g. bleeding disorders) REVAXIS may be administered as a deep subcutaneous (SC) injection.

Contraindications: Hypersensitivity to diphtheria, tetanus or poliomyelitis vaccines or to any other component of the vaccine (including neomycin, streptomycin and polymyxin B). Acute severe febrile illness. Neurological complications following previous immunisation against diphtheria and/or tetanus.

Warnings and Precautions: Prior to immunisation: As with all injectable vaccines, appropriate medical treatment should be readily available in the event of anaphylactic reaction. In order to minimise the risk of adverse events, REVAXIS should not be administered to subjects who completed a primary vaccination course or received a booster of a vaccine containing diphtheria or tetanus toxoids within the previous five years. The immunogenicity of the vaccine could be reduced in immunosuppressed subjects. Where possible, vaccination should be postponed until immune function has recovered. However, vaccination of subjects with chronic immunodeficiency, such as AIDS, is recommended even if the antibody response might be limited. Potential benefits and possible risks should be considered prior to decision to give any vaccine containing tetanus toxoid if Guillain-Barré syndrome or brachial neuritis has occurred following a prior tetanus toxoid vaccination. Administration precautions: REVAXIS must be administered with caution to subjects with thrombocytopenia or a bleeding disorder since bleeding may occur following an IM administration to such subjects. Under these conditions, REVAXIS may be administered as a deep SC injection. Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. Procedures should be in place to prevent falling and injury and to manage syncope. Excipients of known effect: REVAXIS contains 10 µg phenylalanine in each 0.5 mL dose which is equivalent to 0.17 µg/kg for a 60 kg person. Phenylalanine may be harmful for people with phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly. REVAXIS contains 2 mg of alcohol (ethanol) in each 0.5 mL dose. The small amount of alcohol in this medicine will not have any noticeable effects. REVAXIS contains less than 1 mmol of potassium (39 mg) and sodium (23 mg) per dose, that is to say essentially 'potassium-free' and 'sodium-free'.

Interactions: REVAXIS may be administered at the same time as other vaccines or immunoglobulins provided that the injections are made at separate site. Subjects who are taking immunosuppressive agents may not respond to REVAXIS.

Fertility, pregnancy and lactation: No teratogenic effect of vaccines containing diphtheria or tetanus toxoids, or inactivated poliovirus has been observed following use in pregnant women. However, this vaccine should not be administered to pregnant women unless it is considered urgent to boost immunity. REVAXIS may be administered to breastfeeding women.

Adverse Reactions: Very common: Injection site reactions (pain, erythema, induration, oedema and nodule). Common: vertigo, nausea, vomiting, pyrexia and headache. Other Serious Adverse Drug Reactions: *Uncommon:* lymphadenopathy *Frequency not known:* systemic allergic or anaphylactic reactions (including shock) or allergic-type reactions (such as urticaria, rash, face oedema), convulsions, Guillain Barre syndrome, brachial neuritis, transient paraesthesia and hypoesthesia of the vaccinated limb, vasovagal syncope, large injection site reactions (>50 mm) including extensive limb swelling from the injection site beyond one or both joints. *Prescribers should consult the SmPC in relation to other adverse reactions.*

List price: Single pack (one pre-filled syringe): £7.80

Legal Category: POM

Marketing Authorisation Number: PL 23228/0002

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