Prescribing Information: REVAXIS suspension for injection in pre-filled syringe

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

Presentation: 0.5 millilitre single dose of vaccine supplied in a prefilled syringe. Each dose of vaccine contains ≥2 IU of purified diphtheria toxoid, ≥20 IU of purified tetanus toxoid, 40D antigen units of inactivated type 1 polio virus, 8D antigen units of inactivated type 2 polio virus, 32D antigen units of inactivated type 3 polio virus and 0.35 mg of aluminium hydroxide as adsorbent. Excipient with known effect: each dose contains apromimately 10ug of phenylalanine

Indication: Active immunisation against diphtheria, tetanus and poliomyelitis in adults, adolescents and children from six years of age, as a booster following primary vaccination. REVAXIS is not intended for primary immunisation.

Dosage and Administration: Adults, adolescents and children from six years of age should receive one 0.5 mL dose, according to official recommendations. The vaccine should be administered by the intramuscular 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 injection

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

Precautions and Warnings: Appropriate facilities and medication should be available in the event of anaphylaxis. Immunogenicity of the vaccine may be reduced by immunosuppressive treatment or immunodeficiency. Intramuscular injections should be given with care in patients at risk of haemorrhage. Do not administer 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**.** Potential benefits and possible risks should be considered if Guillain-Barré syndrome or brachial neuritis has occurred following a prior tetanus toxoid vaccination**.**

REVAXIS contains 10 microgram phenylalanine in each 0.5 ml dose which is equivalent to 0.17 microgram/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 milligram of alcohol (ethanol) in each 0.5ml dose. The small amount of alcohol in this medicine will not have any noticeable effects.

REVAXIS contains less than 1mmol of potassium (39 mg) and sodium (23 mg) per dose, that is to say essentially 'potassium-free' and 'sodium-free'.

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded

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

REVAXIS 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 side effects include: Injection site reactions (pain, erythema, induration, oedema and nodule) Common side effects include vertigo, nausea, vomiting, pyrexia and headache. Serious side effects have been reported although their frequency is not known. These include systemic allergic or anaphylactic reactions including shock, convulsions, Guillain Barre syndrome, brachial neuritis, transient paraesthesia and hypoesthesia of the vaccinated limb, allergic type reactions, large injection site reactions (>50 mm), diarrhoea, and vasovagal syncope.

For a complete list of undesirable effects please refer to the Summary of Product Characteristics.

List price: Single pack containing one prefilled syringe, basic NHS cost £7.80 per dose

Legal Category: POM

M**arketing Authorisation Number**: PL 46602/0006

Marketing Authorisation Holder: Sanofi Pasteur Europe, 14 Espace Henry Vallée, 69007 Lyon, France

Further information is available from: Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK

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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