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- a high temperature (fever)
- headache

Uncommon side effects (reported by less than 1 in 100 people):
- swollen glands (lymphadenopathy)
- feeling generally unwell (malaise)
- muscle pains (myalgia)

Rare side effects (reported by less than 1 in 1,000 people):
- joint pains (arthralgia)

Additionally, the following side effects with unknown frequency (exact incidence rates cannot be precisely calculated) have been reported during the commercial use of REVAXIS

- pain in the vaccinated limb
- large reactions at the injection site (larger than 5 cm), including extensive limb swelling from the injection site beyond one or both joints. These reactions start within 24-72 hours after vaccination, may be associated with redness, warmth, tenderness or pain at the injection site, and get better within 3-5 days without the need for treatment.
- uncontrollable shivering (chills) and flu-like symptoms. These side effects mostly occur on the same day as the vaccination.
- feeling weak and looking pale (asthenia, pallor). This usually goes away within a few days of the vaccination
- abdominal pain, diarrhoea
- allergic reactions such as hives or skin rash, swelling of the face (facial oedema)
- serious allergic reactions including shock (anaphylactic reactions including shock). Please refer to the paragraph „Serious allergic reactions“ earlier in this section.
- fainting (vasovagal syncope)
- ‘pins and needles’ or numbness in the vaccinated limb (transient paresthesia and hypoesthesia)
- temporary loss of movement or feeling (Guillain-Barré syndrome); loss of movement, pain and numbness of the arm and the shoulder (brachial neuritis); convulsions.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store REVAXIS

Keep this vaccine out of the sight and reach of children.
Store in a refrigerator between 2°C and 8°C. Do not freeze. Discard the vaccine if it has been frozen. Do not use this vaccine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
Do not throw away any medicines via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What REVAXIS contains

The active substances in each dose (0.5 ml) of vaccine are:

Purified Diphtheria Toxoid	not less than 2 IU[1]
Purified Tetanus Toxoid	not less than 20 IU[1]
Inactivated Poliomyelitis virus (cultivated on Vero cells)	
Type 1	29 D antigen units[2]
Type 2	7 D antigen units[2]
Type 3	26 D antigen units[2]
The adsorbent is: aluminium hydroxide	0.35 mg as aluminium

[1] IU is an international unit for measuring vaccine activity
[2] These antigen quantities are strictly the same as those previously expressed as 40-8-32 D-antigen units, for virus type 1, 2 and 3 respectively, when measured by another suitable immunochemical method.

Aluminium hydroxide is included in this vaccine as an adsorbent. Adsorbents are substances included in certain vaccines to accelerate, improve and/or prolong the protective effects of the vaccine.
The other ingredients are:
Phenoxyethanol, ethanol anhydrous, formaldehyde, acetic acid (pH adjuster), sodium hydroxide (pH adjuster), Medium 199 (a mixture of amino acids including phenylalanine, mineral salts, vitamins, polysorbate 80, hydrochloric acid (pH adjuster), sodium hydroxide (pH adjuster) and other substances) and water for injections.

What REVAXIS look s like and contents of the pack

The vaccine’s normal appearance is a cloudy white suspension for injection that may sediment during storage. It is available as a single dose (0.5 ml) pre-filled syringe
- without attached needle – pack size of 1 or 10
- with 1 or 2 separate needles – pack size of 1 or 10
- with attached needle – pack size of 1 or 10

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Sanofi Winthrop Industrie, 82 avenue Raspail, 94250 Gentilly, France

Distributed by:

Sanofi
410 Thames Valley Park Drive
Reading
Berkshire
RG6 1PT, UK
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Manufacturer

The manufacturer responsible for batch release is:
Sanofi Pasteur
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69007 Lyon, France

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Budapest, 1225, Hungary

This medicinal product is authorised in the following Member States of the EEA under the name REVAXIS: Austria, Belgium, Germany, Italy, Ireland, Luxembourg, Portugal, The Netherlands, United Kingdom.

This leaflet was last revised in 11/2024

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