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PACKAGE LEAFLET: INFORMATION FOR THE USER

REVAXiS®

Suspension for injection in pre-filled syringe

Diphtheria, Tetanus and Poliomyelitis (inactivated) Vaccine (adsorbed, reduced antigen(s) content)

Read all of this leaflet carefully before you or your child is vaccinated.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- This vaccine has been prescribed for you or your child. Do not pass it on to others.
- 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.

In this leaflet:

1. WHAT REVAXiS IS AND WHAT IT IS USED FOR

REVAXiS is a vaccine. Vaccines are used to protect against infectious diseases. This vaccine helps boost protection against diphtheria, tetanus and poliomyelitis (polio). When an injection of REVAXiS is given, the body's natural defences will produce protection against these different diseases.

This booster vaccination is for children from the age of 6 years, teenagers and adults who have received this vaccine or a similar vaccine in the past. REVAXiS should not be given as the first vaccination (primary course) against diphtheria, tetanus and poliomyelitis (polio).
REVAXiS will be given according to national recommendations and/or local practice.

2. BEFORE YOU USE REVAXiS

To make sure that REVAXiS is suitable for you or your child, it is important that you tell your doctor, nurse or pharmacist if any points below apply to you or your child. If there is anything you do not understand, ask your doctor, nurse or pharmacist to explain.

Do not use REVAXiS if you or your child:

- is allergic (hypersensitive)
  - to the active substances of REVAXiS (listed in section 6).
  - to any of the other ingredients (listed in section 6).
  - to neomycin, streptomycin and polymyxin B which can be present in trace amounts.
- has ever had an allergic reaction to any vaccine for diphtheria, tetanus or polio.
- has ever had any neurological problems (such as weakness or numbness) after a previous injection of a vaccine against diphtheria or tetanus.
- has an acute severe illness (infection) with a high temperature. The vaccination will be delayed until you/your child has recovered. A minor infection is not usually a reason to postpone vaccination. Your doctor or nurse will decide if you or your child should receive the vaccine.

Take special care with REVAXiS

Tell your doctor or nurse before vaccination if you or your child:

- has a blood disorder where you or your child bruise or bleed easily (such as haemophilia or thrombocytopenia).
- has ever had a temporary loss of movement and feeling in all or part of the body or loss of movement, pain and numbness of the arm and the shoulder after having a vaccine which contains tetanus (Guillain-Barré syndrome or brachial neuritis).
- has had a vaccine for diphtheria or tetanus within the last 5 years. Your doctor will decide on the basis of local recommendations whether you or your child can receive a further injection or not.
- has a poor or reduced immune system, because of a course of medical treatment (e.g., steroids, chemotherapy or radiotherapy), HIV infection or any other illness. The vaccine may not protect as well as it protects people with normal immune systems. The vaccination may be postponed until your/your child's immune system has recovered.

Using other medicines or vaccines

REVAXiS can be given at the same time as other vaccines or immunoglobulins but in different injection sites (e.g. the other arm or leg).

If you or your child is receiving medical treatment that affects the immune system (such as steroids, chemotherapy or radiotherapy), refer to the section "Take special care with REVAXiS".

Tell your doctor, nurse or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

Tell your doctor, nurse or pharmacist if you or your child is pregnant, might be pregnant or is breastfeeding. Your doctor will decide whether or not the vaccination should be delayed.

REVAXIS can be given to women who are breastfeeding.

Driving and using machines

Dizziness (vertigo) has been reported after vaccination. If you feel dizzy after having the vaccine, you should not drive or operate machinery.

3. HOW TO USE REVAXiS

When you or your child will be given the vaccine

REVAXiS is for children from the age of 6 years, teenagers and adults. This vaccine is not suitable for children who are under 6 years old.

REVAXiS is used to boost protection in someone who has received this vaccine or a similar vaccine in the past. Remember that the polio vaccine you had in the past may have been given by injection or by mouth.

This vaccine will be given according to national recommendations and/or local practice.

After an injury, you may need a tetanus vaccination. Your doctor or nurse will give you REVAXiS in case you also need a booster against diphtheria and polio at the same time.

Dosage and method of administration

The vaccination will be given by a doctor or nurse who is trained in the use of vaccines and at a clinic or surgery that is equipped to deal with any uncommon severe allergic reaction to the injection.

Dosage

Children from the age of 6 years, teenagers and adults will receive one injection (0.5 ml dose).

Method of administration

REVAXiS is given as an injection into a muscle, usually in the upper outer part of the arm.

The vaccine is not to be injected directly into any blood vessel or into the skin. In case of blood clotting disorders your doctor may decide to inject deep under the skin.

If you have any further questions on the use of this vaccine, ask your doctor, nurse or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, REVAXiS can cause side effects, although not everybody gets them.

Serious allergic reactions

These reactions are always a rare possibility after receiving a vaccine and may include:

- difficulty in breathing
- blue discolouration of the tongue or lips
- swelling of the face or throat
- low blood pressure (causing dizziness)
- fainting (collapse)

When these signs or symptoms occur they usually develop very quickly after the injection is given and while the person affected is still in the clinic or doctor's surgery.

If any of these symptoms occur after leaving the place where you or your child received the injection, you must consult a doctor IMMEDIATELY.

Other side effects

If you or your child experiences any of the following side effects and it gets serious, tell your doctor, nurse or pharmacist.

During clinical studies, the following side effects were observed:

Very common side effects (reported in more than 1 out of 10 people):

- local reactions at the site of injection: pain, redness, hardening of the skin (induration), swelling or nodule. If these symptoms begin it is usually within 48 hours of the vaccination, lasting for 1 to 2 days.

Common side effects (reported by less than 1 in 10 people):

- dizziness (vertigo)
- feeling sick and being sick (nausea and vomiting)
- 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 have been reported very rarely during the commercial use of REVAXiS; however, exact incidence rates cannot be precisely calculated:

- 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.

5. HOW TO STORE REVAXiS

Keep out of the reach and sight 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 REVAXiS after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What REVAXiS contains

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

Purified Diphtheria Toxoid	not less than 2 IU*
Purified Tetanus Toxoid	not less than 20 IU*
Inactivated Poliomyelitis virus (produced in Vero cells)	
Type 1	40 D antigen units**
Type 2	8 D antigen units**
Type 3	32 D antigen units**
The adsorbent is: aluminium hydroxide	0.35 mg as aluminium

* IU is an international unit for measuring vaccine activity
** an antigen unit is for determination of antigen amount

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, formaldehyde, Medium 199 (a mixture of amino acids including phenylalanine, mineral salts, vitamins, polysorbate 80 and other substances) and water for injections.

What REVAXiS looks 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, 10 or 20
- with 1 or 2 separate needles – pack size of 1 or 10
- with attached needle – pack size of 1, 10 or 20

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
The Marketing Authorisation Holder in the UK is:
Sanofi Pasteur MSD Limited, Mallards Reach, Bridge Avenue
Maidenhead, Berkshire, SL6 1QP

The Marketing Authorisation Holder in Ireland is:
Sanofi Pasteur MSD Limited, Block A, Second Floor,
Cookstown Court, Old Belgard Road, Tallaght, Dublin 24.

Manufacturer
The manufacturer responsible for batch release is: Sanofi Pasteur S.A., Campus Mérieux, 1541 avenue Marcel Mérieux, F-69280 Marcy l'Etoile, Lyon

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

This leaflet was last approved in August 2008.

The following information is intended for medical or healthcare professionals only:

Instructions for use

For needle free syringes, the needle should be pushed firmly on to the end of the pre-filled syringe and rotated through 90 degrees.
Shake the pre-filled syringe well to distribute uniformly the suspension before administering the vaccine.
Parenteral biological products should be inspected visually for extraneous particulate matter and/or discolouration prior to administration. In the event of either being observed, discard the vaccine.
In the absence of compatibility studies, the vaccine must not be mixed with other medicinal products.
See also section 3. HOW TO USE REVAXiS

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