

## Package leaflet: Information for the user

### REPEVAX®

#### Suspension for injection in pre-filled syringe

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

**Read all of this leaflet carefully before you or your child is vaccinated because it contains important information for you.**

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

#### **What is in this leaflet:**

1. What REPEVAX is and what it is used for
2. What you need to know before you use REPEVAX
3. How to use REPEVAX
4. Possible side effects
5. How to store REPEVAX
6. Contents of the pack and other information

#### **1. What REPEVAX is and what it is used for**

REPEVAX is a vaccine. Vaccines are used to protect against infectious diseases. They work by causing the body to produce its own protection against the bacteria and viruses that cause the targeted diseases.

This vaccine is used to boost protection against diphtheria, tetanus, pertussis (whooping cough) and poliomyelitis (polio) in children from the age of three years, teenagers and adults following a complete primary course of vaccination.

#### **Limitations in the protection provided**

REPEVAX will only prevent these diseases if they are caused by the bacteria or viruses targeted by the vaccine. You or your child could still get similar diseases if they are caused by other bacteria or viruses.

REPEVAX does not contain any live bacteria or viruses and it cannot cause any of the infectious diseases against which it protects.

Remember that no vaccine can provide complete, life long protection in all people who are vaccinated.

#### **2. What you need to know before you use REPEVAX**

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

### **Do not use REPEVAX if you or your child**

- Has had an allergic reaction:
  - to diphtheria, tetanus, pertussis or poliomyelitis vaccines
  - to any of the other ingredients (listed in section 6)
  - to any residual component carried over from manufacture (formaldehyde, glutaraldehyde, streptomycin, neomycin, polymyxin B and bovine serum albumin) which may be present in trace amounts.
- has ever had
  - a severe reaction affecting the brain within one week after a previous dose of a whooping cough vaccine
- has an acute illness with or without fever. The vaccination should be delayed until you or your child has recovered. A minor illness without fever is not usually a reason to defer vaccination. Your doctor will determine if you or your child should receive REPEVAX.

### **Warnings and precautions**

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

- received a booster dose of a vaccine for diphtheria and tetanus within the last 4 weeks. In this case you or your child should not receive REPEVAX and your doctor will decide on the basis of official recommendations when you or your child can receive a further injection.
- ever had a Guillain-Barré syndrome (temporary loss of movement and feeling in all or part of the body) or brachial neuritis (loss of movement, pain and numbness of the arm and the shoulder) following a previous dose of a tetanus containing vaccine. Your doctor will decide if you or your child should receive REPEVAX.
- a progressive illness affecting the brain/nerves or uncontrolled fits. Your doctor will first start treatment and vaccinate when the condition has stabilized.
- a poor or reduced immune system, due to:
  - medication (e.g. steroids, chemotherapy or radiotherapy)
  - HIV infection or AIDS
  - any other illness.

The vaccine may not protect as well as it protects people whose immune system is healthy. If possible, vaccination should be postponed until the end of such disease or treatment.

- any problems with the blood that causes easy bruising, or bleeding for a long time after minor cuts (for instance due to a blood disorder such as haemophilia or thrombocytopenia or treatment with blood thinning medicines).

### **Other medicines or vaccines and REPEVAX**

As REPEVAX does not contain any live bacteria or viruses it can generally be given at the same time as other vaccines or immunoglobulins, but at a different injection site. Studies have demonstrated that REPEVAX can be used at the same time as any of the following vaccines: an inactivated influenza vaccine, a hepatitis B vaccine, and a recombinant Human Papillomavirus vaccine respectively. Injections of more than one vaccine at the same time will be given in different limbs.

If you or your child is receiving medical treatment affecting your or your child's blood or immune system (such as blood thinning medicines, steroids, chemotherapy), please refer to the section "Warnings and precautions" above.

Tell your doctor or pharmacist if you or your child is taking, has recently taken or might take any other medicines.

### **Pregnancy, breast-feeding and fertility**

Tell your doctor or nurse if you or your child is pregnant or breast-feeding, think you or your child might be pregnant or planning to have a baby. Your doctor or nurse can advise you whether or not vaccination should be delayed. The use of REPEVAX is not recommended during pregnancy.

### **Driving and using machines:**

It has not been studied if the vaccine affects the ability to drive or use machines.

## **3. How to use REPEVAX**

### **When you or your child will be given the vaccine**

#### Vaccination history

Your doctor will determine if REPEVAX is suitable for you or your child, depending on:

- what vaccines have been given to you or your child in the past
- how many doses of similar vaccines have been given to you or your child in the past
- when the last dose of a similar vaccine was given to you or your child

You or your child must have had the complete primary courses of diphtheria, tetanus and polio vaccines before having REPEVAX.

It is safe to have REPEVAX if you or your child has not had the complete primary course of whooping cough vaccines but protection may not be as good as in people who have already had the whooping cough vaccine.

Your doctor will decide how long you have to wait between vaccinations.

### **Dosage and method of administration**

#### Who will give you REPEVAX?

REPEVAX should be given by healthcare professionals who have been trained in the use of vaccines and at a clinic or surgery that is equipped to deal with any rare severe allergic reaction to the vaccine.

#### Dosage

All age groups for whom REPEVAX is indicated will receive one injection (half a millilitre).

In case you or your child experiences an injury which requires preventative action for tetanus disease, your doctor may decide to give REPEVAX with or without tetanus immunoglobulin.

### **Use in children and adolescents**

REPEVAX should not be used in children under 3 years of age.

Children from the age of 3 years onwards and adolescents should receive the same dosage as adults.

#### Method of administration

Your doctor or nurse will give you the vaccine into a muscle in the upper outer part of the arm (deltoid muscle).

Your doctor or nurse will **not** give you the vaccine into a blood vessel, into the buttocks or under the skin. In case of blood clotting disorders they may decide to inject under the skin, although this might result in more local side effects, including a small lump under the skin.

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

#### **4. Possible side effects**

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

##### **Serious allergic reactions**

Serious allergic reactions are a very rare possibility after receiving any vaccine. These reactions may include:

- difficulty in breathing
- blueness of the tongue or lips
- a rash
- swelling of the face or throat
- low blood pressure causing dizziness or collapse.

When these signs or symptoms occur they usually develop very quickly after the injection is given and while you or your child 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**

The following side effects were observed during clinical studies carried out in specific age groups.

##### **In children 3 to 6 years of age**

Very common (in more than 1 in 10 children): pain, swelling and redness in the area where the vaccine was injected, tiredness, fever (a temperature at or above 37.5°C), irritability.

Common (in less than 1 in 10, but more than 1 in 100 children): bruising, itching and skin inflammation in the area where the vaccine was injected, headache, nausea, vomiting, diarrhoea, rashes, aching or swollen joints

In adolescents (11 years of age and older) and adults

Teenagers are a little more likely than adults to have side effects. Most side effects occur within the first 3 days after vaccination.

Very common (in more than 1 in 10 people): pain, swelling and redness in the area where the vaccine was injected, headache, nausea, aching or swollen joints, aching muscles, weakness, and chills.

Common (in less than 1 in 10, but more than 1 in 100 people): vomiting, diarrhoea, fever (a temperature at or above 38.0°C).

The following additional adverse events have been reported in the various recommended age groups during the commercial use of REPEVAX. The frequency of these adverse events cannot be precisely calculated, as it would be based on voluntary reporting in relation to the estimated number of vaccinated persons.

Lymph node disorder, allergic/serious allergic reactions, fits (convulsions), fainting, paralysis of part or all the body (Guillain-Barré syndrome), facial paralysis, inflammation of the spinal cord, inflammation of the nerves in the arm (brachial neuritis), temporary loss or alteration of sensation in vaccinated limb, dizziness, pain in vaccinated limb, extensive limb swelling (frequently associated with redness, and sometimes with blisters), feeling ill, pale skin, a hard lump (induration) in the area where vaccine was injected.

**If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.**

## 5. How to store REPEVAX

Keep out of the sight and reach of children.

REPEVAX must not be used after the expiry date which is stated on the label after "EXP". The expiry date refers to the last day of that month.

Store in a refrigerator (at 2°C to 8°C). Do not freeze. Discard the vaccine if it has been frozen.

Keep the container in the outer carton in order to protect from light.

Do not throw away any medicines via wastewater 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 REPEVAX contains

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

Diphtheria Toxoid	not less than 2 International Units (2 Lf)
Tetanus Toxoid	not less than 20 International Units (5 Lf)
Pertussis Antigens:	
Pertussis Toxoid	2.5 micrograms
Filamentous Haemagglutinin	5 micrograms
Pertactin	3 micrograms
Fimbriae Types 2 and 3	5 micrograms

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
Adsorbed on aluminium phosphate	1.5 mg (0.33 mg aluminium)

The other ingredients are: phenoxyethanol, polysorbate 80, water for injections

### What REPEVAX looks like and contents of the pack

REPEVAX is presented as a suspension for injection in pre-filled syringes (0.5 mL):

- 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.

The normal appearance of the vaccine is a uniform cloudy white suspension, which may sediment during storage. After shaking well it is a uniformly white liquid.

### Marketing Authorisation Holder and Manufacturer

[TO BE COMPLETED LOCALLY]

The manufacturer responsible for batch release is:

Sanofi Pasteur  
2, avenue pont Pasteur  
69007 Lyon  
France

### This medicinal product is authorised in the Member States of the EEA under the following names:

Austria, Denmark, Finland, France, Germany, Greece,  
Iceland, Ireland, Norway, Portugal, United Kingdom: REPEVAX

Belgium, Luxembourg, Netherlands: TRIAXIS POLIO

### This leaflet was last revised on

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The following information is intended for healthcare professionals only:

#### Instructions for use

In the absence of compatibility studies, REPEVAX must not be mixed with other medicinal products.

Parenteral products should be inspected visually for extraneous particulate matter and/or discolouration prior to administration. If these conditions exist, the product should not be administered.

For needle-free syringes, the needle should be pushed firmly onto the end of the pre-filled syringe and rotated through 90 degrees.

Needles should not be recapped.