Package leaflet: Information for the user

REPEVAX®

Suspension for injection

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. See section 4.

What is in this leaflet:

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).

Fainting can occur following, or even before, any needle injection. Therefore tell the doctor or nurse if you or your child fainted in connection with a previous injection.

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.

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

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.

Your doctor will give you advice on repeat vaccination.

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), diarrhoea.

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, rashes, aching or swollen joints, irritability.

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, abdominal pain.

Reporting side effects

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

In Ireland

You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

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 vials (0.5 mL):

- pack size of 1 (with or without empty polypropylene syringe and two needles), 5, 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

The Marketing Authorisation Holder in the Ireland is:

Sanofi Pasteur MSD Limited
Block A, Second Floor
Cookstown Court
Old Belgard Road
Tallaght
Dublin 24

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 in 01/2015

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.

When administering a dose from a stoppered vial, do not remove either the stopper or the metal seal holding it in place.

Needles should not be recapped.